UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to_____.

Commission file number: 001-35005

ASSEMBLY BIOSCIENCES, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**20-8729264**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
331 Oyster Point Blvd., Fourth Floor South San Francisco, California	**94080**
(Address of principal executive offices)	(zip code)

(833) 509-4583
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001	ASMB	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☒
Non-accelerated Filer	☐	Smaller Reporting Company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 2, 2020, there were 33,022,336 shares of the registrant's common stock outstanding.

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PART I - FINANCIAL INFORMATION
Item 1. Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 58,311	$ 46,732
Marketable securities	179,630	227,311
Accounts receivable from collaboration	3,590	3,374
Prepaid expenses and other current assets	4,856	5,363
Total current assets	246,387	282,780
Property and equipment, net	1,904	1,830
Operating lease right-of-use (ROU) assets	10,397	11,975
Other assets	5,980	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 306,306**	**$ 339,907**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,611	$ 1,731
Accrued clinical expenses	4,451	4,826
Other accrued expenses	7,404	8,286
Deferred revenue - short-term	—	6,411
Operating lease liabilities - short-term	3,338	3,186
Total current liabilities	16,804	24,440
Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	8,987	30,637
Operating lease liabilities - long-term	7,435	9,082
Total liabilities	**35,757**	**66,690**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 32,924,536 and 32,558,307 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	33	32
Additional paid-in capital	732,829	712,807
Accumulated other comprehensive loss	(158)	(201)
Accumulated deficit	(462,155)	(439,421)
Total stockholders' equity	270,549	273,217
Total liabilities and stockholders' equity	**$ 306,306**	**$ 339,907**

See Accompanying Notes to Condensed Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands except for share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 34,611	$ 4,231	$ 78,068	$ 11,197
Operating expenses:				
Research and development	26,941	21,736	73,314	63,141
General and administrative	11,689	8,488	29,888	22,085
Total operating expenses	38,630	30,224	103,202	85,226
Loss from operations	**(4,019)**	**(25,993)**	**(25,134)**	**(74,029)**
Other income				
Interest and other income, net	670	983	2,400	3,446
Total other income	670	983	2,400	3,446
Loss before income taxes	**(3,349)**	**(25,010)**	**(22,734)**	**(70,583)**
Income tax benefit	—	15	—	33
Net loss	**$ (3,349)**	**$ (24,995)**	**$ (22,734)**	**$ (70,550)**
Other comprehensive (loss) income				
Unrealized (loss) gain on marketable securities, net of tax	(262)	(18)	43	142
Comprehensive loss	**$ (3,611)**	**$ (25,013)**	**$ (22,691)**	**$ (70,408)**
Net loss per share, basic and diluted	$ (0.09)	$ (0.96)	$ (0.64)	$ (2.74)
Weighted average common shares outstanding, basic and diluted	35,506,042	25,912,568	35,321,393	25,765,414

See Accompanying Notes to Condensed Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (22,734)	$ (70,550)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	377	377
Stock-based compensation	18,106	14,049
Net accretion and amortization of investments in marketable debt securities	(80)	(1,503)
Non-cash rent expense	3,463	3,344
Deferred income tax benefit	—	(33)
Loss on disposal of fixed assets	—	102
Other	—	18
Changes in operating assets and liabilities:		
Accounts receivable from collaboration	(216)	(514)
Prepaid expenses and other current assets	507	(3,763)
Other assets	(4,296)	1,677
Accounts payable	(120)	(984)
Accrued clinical expenses	(375)	670
Other accrued expenses	(877)	(1,000)
Deferred revenue	(28,061)	(2,241)
Operating lease liabilities	(3,382)	(3,188)
Net cash used in operating activities	(37,688)	(63,539)
Cash flows from investing activities		
Purchases of property and equipment	(470)	(1,539)
Purchases of marketable securities	(153,022)	(149,327)
Proceeds from maturities of marketable securities	165,252	166,911
Proceeds from sale of marketable securities	35,595	28,659
Net cash provided by investing activities	47,355	44,704
Cash flows from financing activities		
Proceeds from the exercise of stock options	1,445	1,716
Proceeds from the issuance of common stock under Employee Stock Purchase Plan (ESPP)	467	515
Net cash provided by financing activities	1,912	2,231
Net increase (decrease) in cash and cash equivalents	11,579	(16,604)
Cash and cash equivalents at the beginning of the period	46,732	41,471
Cash and cash equivalents at the end of the period	**$ 58,311**	**$ 24,867**
Supplemental non-cash investing and financing activities		
Operating lease liabilities arising from obtaining ROU assets	$ 1,063	$ 15,261

See Accompanying Notes to Condensed Consolidated Financial Statements

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In thousands except for share amounts)
(Unaudited)

	For the Three Month Period					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2020	**32,807,519**	**$ 33**	**$ 725,784**	**$ 104**	**$ (458,806)**	**$ 267,115**
Issuance of common stock upon exercise of stock options	81,066	—	843	—	—	843
Issuance of shares of common stock for settlement of restricted stock units (RSUs)	35,951	—	—	—	—	—
Unrealized loss on marketable debt securities	—	—	—	(262)	—	(262)
Stock-based compensation	—	—	6,202	—	—	6,202
Net loss	—	—	—	—	(3,349)	(3,349)
Balance as of September 30, 2020	**32,924,536**	**$ 33**	**$ 732,829**	**$ (158)**	**$ (462,155)**	**$ 270,549**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2019	**25,646,783**	**$ 26**	**$ 562,210**	**$ (187)**	**$ (387,342)**	**$ 174,707**
Issuance of common stock upon exercise of stock options	192,606	—	1,385	—	—	1,385
Issuance of shares of common stock for settlement of RSUs	33,334	—	—	—	—	—
Unrealized loss on marketable debt securities, net of tax	—	—	—	(18)	—	(18)
Stock-based compensation	—	—	5,410	—	—	5,410
Net loss	—	—	—	—	(24,995)	(24,995)
Balance as of September 30, 2019	**25,872,723**	**$ 26**	**$ 569,005**	**$ (205)**	**$ (412,337)**	**$ 156,489**

	For the Nine Month Period					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2019	**32,558,307**	**$ 32**	**$ 712,807**	**$ (201)**	**$ (439,421)**	**$ 273,217**
Issuance of common stock upon exercise of stock options	172,779	1	1,444	—	—	1,445
Issuance of common stock under ESPP	42,266	—	467	—	—	467
Issuance of shares of common stock for settlement of RSUs	151,184	—	—	—	—	—
Unrealized gain on marketable debt securities	—	—	—	43	—	43
Stock-based compensation	—	—	18,111	—	—	18,111
Net loss	—	—	—	—	(22,734)	(22,734)
Balance as of September 30, 2020	**32,924,536**	**$ 33**	**$ 732,829**	**$ (158)**	**$ (462,155)**	**$ 270,549**

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2018	**25,495,425**	**$ 25**	**$ 552,762**	**$ (347)**	**$ (341,787)**	**$ 210,653**
Issuance of common stock upon exercise of stock options	243,481	—	1,716	—	—	1,716
Issuance of common stock under ESPP	36,804	—	515	—	—	515
Issuance of shares of common stock for settlement of RSUs	97,013	1	(1)	—	—	—
Settlement of RSUs for cash	—	—	(4)	—	—	(4)
Unrealized gain on marketable debt securities, net of tax	—	—	—	142	—	142
Stock-based compensation	—	—	14,017	—	—	14,017
Net loss	—	—	—	—	(70,550)	(70,550)
Balance as of September 30, 2019	**25,872,723**	**$ 26**	**$ 569,005**	**$ (205)**	**$ (412,337)**	**$ 156,489**

See Accompanying Notes to Condensed Consolidated Financial Statements

Note 1 - Nature of Business

Overview

Assembly Biosciences, Inc., together with its subsidiaries (Assembly or the Company), incorporated in Delaware in October 2005, is a clinical-stage biotechnology company advancing two innovative programs: a novel class of oral therapeutic candidates targeting chronic hepatitis B virus (HBV) infection and a novel class of oral live microbial biotherapeutic candidates, which are designed to treat disorders associated with the microbiome. The Company operates in one segment and is headquartered in South San Francisco, California, with operations in California, Connecticut and China.

The Company's HBV Cure program is pursuing multiple drug candidates that inhibit the HBV replication cycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of increasing the current low cure rates for patients with chronic HBV infection. Assembly has discovered several novel core inhibitors, which are small molecules that directly target and allosterically modify the HBV core protein.

The Company's Microbiome program is centered on a fully integrated platform that includes a biological function-based strain isolation, identification, characterization and selection process, methods for strain purification and growth under conditions compliant with current Good Manufacturing Practice (cGMP) requirements. That platform is complemented by a licensed patented delivery system, GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal (GI) tract. Using the Company's microbiome platform, the Company is exploring product candidates for multiple disease indications, including ulcerative colitis (UC), Crohn's disease and irritable bowel syndrome (IBS) in connection with its Research, Development, Collaboration and License Agreement (the Allergan Agreement) with Allergan Pharmaceuticals International Limited (Allergan), which was acquired by AbbVie Inc. (AbbVie). In June 2020, AbbVie made a strategic portfolio decision to terminate the Allergan Agreement effective on October 10, 2020 (see Note 8). Assembly is also exploring the microbiome in connection with immune-mediated and metabolic disorders and oncology.

Liquidity

The Company has not derived any revenue from product sales to date and currently has no approved products. Once a product has been developed, it will need to be approved for sale by the U.S. Food and Drug Administration (FDA) or an applicable foreign regulatory agency. Since inception, the Company's operations have been financed primarily through the sale of equity securities, proceeds from the exercise of warrants and stock options, issuance of debt, an upfront payment related to the Allergan Agreement and an upfront payment related to the Company's Collaboration Agreement (the BeiGene Agreement) with BeiGene, Ltd. (BeiGene). The Company has incurred losses from operations since inception and expects to continue to incur substantial losses for the next several years as it continues its product development efforts. Management believes the Company currently has sufficient funds to meet its operating requirements for at least the next 12 months following the date that these unaudited condensed consolidated interim financial statements are issued. If the Company cannot generate significant cash from its operations, it intends to obtain any additional funding it requires through strategic relationships, public or private equity or debt financings, grants or other arrangements (see Note 6 for recent sales of common stock). The Company cannot assure such funding will be available on reasonable terms, if at all. Market volatility resulting from the global novel coronavirus disease (COVID-19) pandemic or other factors could also adversely impact the Company's ability to access capital when and as needed.

If the Company is unable to generate sufficient revenue from its collaborations, secure additional sources of funding or receive full and timely collections of amounts due, it may be necessary to significantly reduce its current rate of spending through reductions in staff and delaying, scaling back, or stopping certain research and development programs, including more costly clinical trials.

Note 2 - Summary of Significant Accounting Policies and Recent Accounting Pronouncements

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company and its subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Rule 10-01 of Regulation S-X of the U.S. Securities and Exchange Commission (SEC). In management's opinion, the unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and include normal recurring adjustments necessary for the fair presentation of the Company's financial position and its results of operations and comprehensive loss and its cash flows for the periods presented. These statements do not include all disclosures required by U.S. GAAP and should be read in conjunction with the Company's audited consolidated financial statements and accompanying notes for the fiscal year ended December 31, 2019, which are contained in the Company's Annual Report on Form 10-K as filed with the SEC on March 4, 2020. The results for the three and nine months ended September 30, 2020 are not necessarily indicative of results to be expected for the entire year ending December 31, 2020 or future operating periods.

Use of Estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that may affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Significant estimates inherent in the preparation of the accompanying unaudited condensed consolidated financial statements include revenue recognition, clinical trial accruals, recoverability and useful lives (indefinite or finite) of intangible assets, assessment of impairment of goodwill, provisions for income taxes, amounts receivable and recognized as revenue under the Company's collaboration agreements, measurement of operating lease liabilities, and the fair value of stock options, stock appreciation rights, and restricted stock units (RSUs) granted to employees, directors and consultants.

The Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that these external factors could have an effect on the Company's estimates and could cause actual results to differ materially from those estimates and assumptions.

Other Risks and Uncertainties

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. To date, the Company's operations have not been significantly impacted by the COVID-19 pandemic. However, the Company cannot at this time predict the specific extent, duration, or full impact the COVID-19 pandemic will have on its business, operations, strategy, prospects and financial condition and results. The impact of the COVID-19 pandemic on the Company's financial performance will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

Revenue Recognition and Accounts Receivable from Collaboration

We analyze our collaboration arrangements to assess whether such arrangements, or transactions between arrangement participants, involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities or are more akin to a vendor-customer relationship. In making this evaluation, we consider whether the activities of the collaboration are considered to be distinct and deemed to be within the scope of the collaborative arrangement guidance and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of the revenue with contracts with customers guidance. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement.

For elements of collaboration arrangements that are not accounted for pursuant to the revenue from contracts with customers guidance, an appropriate recognition method is determined and applied consistently, generally by analogy to the revenue from contracts with customers guidance. Amounts related to transactions with a counterparty in a collaborative arrangement that is not a customer are presented as collaboration revenue and on a separate line item from revenue recognized from contracts with customers, if any, in the Company's consolidated statements of operations and comprehensive loss.

Under certain collaborative arrangements, the Company has been reimbursed for a portion of its research and development expenses or participates in the cost-sharing of such research and development expenses. Such reimbursements and cost-sharing arrangements are reflected as a reduction of research and development expense in the Company's condensed consolidated statements of operations and comprehensive loss, as the Company does not consider performing these activities for reimbursement to be a part of its ongoing major or central operations.

For arrangements or transactions between arrangement participants determined to be within the scope of the contracts with customers guidance, the Company evaluates the term of the arrangement and recognizes revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company has provided standard indemnification and protection of licensed intellectual property for its customer. These provisions are part of assurance that the licenses meet the agreements, representations and are not obligations to provide goods or services.

The Company only applies the five-step model to contracts when it is probable the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation. The Company recognizes the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied as revenue.

Upfront License Fees

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments

Depending on facts and circumstances, the Company may record revenues from certain milestones in a reporting period before the milestone is achieved if the Company concludes achievement of the milestone is probable and recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company records a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. The Company re-evaluates the probability of achievement of such milestones and any related constraint each reporting period. The Company adjusts its estimate of the overall transaction price, including the amount of collaborative revenue that was recorded, if necessary.

Sales-based Milestone and Royalty Payments

The Company's customer may be required to pay the Company sales-based milestone payments or royalties on future sales of commercial products. The Company recognizes revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the collaborator's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the Company's licensed intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

The Company receives payments from its customer based on billing schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under the arrangement. If the related performance obligation is expected to be satisfied within the next twelve months, these amounts will be classified in current liabilities. The Company recognizes a contract asset relating to its conditional right to consideration that is not subject to a constraint. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

A net contract asset or liability is presented for each contract with a customer. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Income Taxes

In March 2020, the Families First Coronavirus Response Act (FFCR Act) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property.

In June 2020, Assembly Bill 85 (A.B. 85) was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

The FFCR Act, CARES Act and A.B. 85 did not have a material impact on the Company's condensed consolidated financial statements as of September 30, 2020; however, the Company continues to examine the impacts the FFCR Act, CARES Act and A.B. 85 may have on its business, results of operations, financial condition and liquidity.

Net Loss per Share

Basic net loss per common share excludes dilution and is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the entity unless inclusion of such shares would be anti-dilutive.

In December 2019, the Company sold 6,287,878 shares of common stock as well as pre-funded warrants to purchase up to 2,424,242 shares of common stock (see Note 6). The pre-funded warrants are exercisable for shares of common stock at an exercise price of $0.001 per share. The shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing earnings per share, because the shares may be issued for little or no consideration, are fully vested, and are exercisable after the original issuance date.

A reconciliation of the numerators and the denominators of the basic and diluted net loss per common share computations is as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (3,349)	$ (24,995)	$ (22,734)	$ (70,550)
Denominator:				
Weighted average common shares and pre-funded warrants outstanding - basic and diluted	35,506,042	25,912,568	35,321,393	25,765,414
Net loss per share - basic and diluted	$ (0.09)	$ (0.96)	$ (0.64)	$ (2.74)

Securities excluded from the computation of diluted loss per share because including them would have been antidilutive are as follows:

	September 30,	
	2020	2019
Warrants to purchase common stock	-	15,296
Options to purchase common stock	6,660,918	5,462,773
Common stock subject to purchase under our ESPP	25,192	17,018
Unvested RSUs	851,589	668,515
Total	7,537,699	6,163,602

Adoption of Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board (FASB) issued ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Under the amendments in ASU 2017-04, an entity should recognize an impairment charge for the amount by which the carrying amount of a reporting unit exceeds its fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. The updated guidance requires a prospective adoption. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates* (ASU 2019-10), which deferred the effective date of this standard for all entities except SEC filers that are not smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted for goodwill impairment tests performed on testing dates after January 1, 2017. The Company early adopted ASU 2017-04 effective January 1, 2020. The adoption of this standard had no material impact on the Company’s condensed consolidated financial statements.

On January 1, 2020, the Company adopted ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. The adoption of this standard had no material impact on the Company’s condensed consolidated financial statements and related disclosures.

On January 1, 2020, the Company adopted ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. The standard adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606 and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the

collaborative arrangement participant is not a customer. Amendments in the standard should be applied retrospectively to the date of initial application of Topic 606, but entities may elect to apply the amendments in Topic 808 retrospectively either to all contracts or only to contracts that are not completed at the date of initial application of Topic 606, and should disclose the election. An entity may also elect to apply the practical expedient for contract modifications that is permitted for entities using the modified retrospective transition method in Topic 606. The adoption of this standard had no impact on the Company's condensed consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* (ASU 2019-12), which eliminates certain exceptions to the guidance in *Income Taxes (Topic 740)* related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard is effective for fiscal years beginning after December 15, 2020 and interim periods within those fiscal years. Early adoption is permitted in an interim or annual period. Entities that elect to early adopt the amendments in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. Additionally, entities that elect early adoption must adopt all the amendments in the same period. Entities will apply the guidance prospectively, except for certain amendments. The Company early adopted ASU 2019-12 effective January 1, 2020. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. In April, May and November 2019, the FASB issued additional amendments to the new guidance related to transition and clarification. In November 2019, the FASB issued ASU 2019-10, which deferred the effective date of this standard for all entities except SEC filers that are not smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. The Company is evaluating this new accounting standard but currently does not expect the adoption of this standard to have a material impact on its condensed consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* (ASU 2020-06), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. Specifically, ASU 2020-06 simplifies accounting for convertible instruments by removing major separation models in ASC 470-20 that require separate accounting for embedded conversion features. The ASU also removes certain settlement conditions in ASC 815-40 that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for the scope exception and simplifies the diluted EPS calculation in certain areas. The ASU is effective for interim and annual periods beginning after December 15, 2021, with early adoption permitted after December 15, 2020. Adoption of the ASU can either be on a modified retrospective or full retrospective basis. The Company is currently evaluating the impacts of ASU 2020-06 on its condensed consolidated financial statements and related disclosures.

Note 3 – Investments in Marketable Securities

The carrying amounts of cash equivalents and marketable securities approximate their fair value based upon quoted market prices. Certain of the Company's financial instruments are not measured at fair value on a recurring basis, but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash, accounts receivable, accounts payable, accrued expenses, lease liability-short term and deferred revenue-short term.

The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical instruments.

Level 2: Quoted prices for similar instruments that are directly or indirectly observable in the marketplace.

Level 3: Significant unobservable inputs that are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

Investments in marketable securities consisted of the following (in thousands):

	September 30, 2020			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash equivalents				
Money market funds	$ 56,444	$ —	$ —	$ 56,444
Total cash equivalents	56,444	—	—	56,444
Short-term investments				
U.S. and foreign corporate debt securities	36,739	48	(1)	36,786
Asset-backed securities	13,394	16	(1)	13,409
U.S. treasury securities	48,018	69	—	48,087
U.S. and foreign commercial paper	81,348	—	—	81,348
Total short-term investments	179,499	133	(2)	179,630
Total cash equivalents and investments	$ 235,943	$ 133	$ (2)	$ 236,074

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gain (1)	Gross Unrealized Loss (1)	Fair Value
Cash equivalents				
Money market funds	$ 33,095	$ —	$ —	$ 33,095
U.S. and foreign corporate debt securities	5,000	—	(1)	4,999
U.S. and foreign commercial paper	4,484	—	—	4,484
Total cash equivalents	42,579	—	(1)	42,578
Short-term investments				
U.S. and foreign corporate debt securities	72,452	38	(4)	72,486
Asset-backed securities	34,008	17	—	34,025
U.S. treasury securities	44,692	24	(2)	44,714
U.S. and foreign commercial paper	76,086	—	—	76,086
Total short-term investments	227,238	79	(6)	227,311
Total cash equivalents and investments	$ 269,817	$ 79	$ (7)	$ 269,889

(1) Gross unrealized gain (loss) is pre-tax.

The contractual term to maturity of short-term marketable securities held by the Company as of September 30, 2020 is less than one year. There were no long-term marketable securities held by the Company as of September 30, 2020.

Realized gains and losses for the three and nine months ended September 30, 2020 and 2019 were not significant. None of the Company's investments have been in a continuous unrealized loss position for more than 12 months as of September 30, 2020.

The following tables present the fair value of the Company's financial assets measured at fair value on a recurring basis (in thousands):

	September 30, 2020			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 56,444	$ —	$ —	$ 56,444
Total cash equivalents	56,444	—	—	56,444
Short-term investments				
U.S. and foreign corporate debt securities	—	36,786	—	36,786
Asset-backed securities	—	13,409	—	13,409
U.S. treasury securities	—	48,087	—	48,087
U.S. and foreign commercial paper	—	81,348	—	81,348
Total short-term investments	—	179,630	—	179,630
Total assets measured at fair value	$ 56,444	$ 179,630	$ —	$ 236,074

	December 31, 2019			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents				
Money market fund	$ 33,095	$ —	$ —	$ 33,095
U.S. and foreign corporate debt securities	—	4,999	—	4,999
U.S. and foreign commercial paper	—	4,484	—	4,484
Total cash equivalents	33,095	9,483	—	42,578
Short-term investments				
U.S. and foreign corporate debt securities	—	72,486	—	72,486
Asset-backed securities	—	34,025	—	34,025
U.S. treasury securities	—	44,714	—	44,714
U.S. and foreign commercial paper	—	76,086	—	76,086
Total short-term investments	—	227,311	—	227,311
Total assets measured at fair value	$ 33,095	$ 236,794	$ —	$ 269,889

The Company estimates the fair value of its U.S. and foreign corporate debt securities, asset-backed securities, U.S. treasury securities and U.S. and foreign commercial paper by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data, and other observable inputs.

There were no transfers between Level 1, Level 2 or Level 3 during the periods presented.

Note 4 - Property and Equipment, Net

Property and equipment consist of the following (in thousands):

	Useful life (Years)	September 30, 2020	December 31, 2019
Lab equipment	3 to 5	$ 292	$ 247
Office equipment	7	699	699
Leasehold improvement	1 to 5	2,490	2,084
Total property and equipment		3,481	3,030
Less: Accumulated depreciation and amortization		(1,577)	(1,200)
Property and equipment, net		$ 1,904	$ 1,830

Depreciation expense was $0.1 million and $0.4 million for the three and nine months ended September 30, 2020 and 2019, respectively and was recorded in both research and development expense and general and administrative expense in the unaudited condensed consolidated statements of operations and comprehensive loss. Substantially all of the Company's property and equipment is located in the U.S.

Note 5 – Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued expenses:		
Accrued compensation	$ 6,172	$ 5,312
Accrued restructuring charges	697	2,094
Accrued professional fees and other	535	880
Total accrued expenses	$ 7,404	$ 8,286

Accrued restructuring charges relate to the Company's decision to relocate its headquarters to South San Francisco, California, which was approved by the Board of Directors in November 2019 and effective January 1, 2020. The Company accrued restructuring charges of $2.1 million in 2019 related to one-time severance payments and other employee-related costs associated with the relocation plan. This represents the total amount expected to be incurred in connection with the relocation and is expected to be fully paid in 2020.

Note 6 – Stockholders' Equity

The Company is authorized to issue 5,000,000 shares of preferred stock as of September 30, 2020 and December 31, 2019, respectively. As of September 30, 2020 and December 31, 2019, no shares of preferred stock were issued and outstanding. The Company is authorized to issue 100,000,000 shares of common stock as of September 30, 2020 and December 31, 2019, respectively.

Sale of Common Stock and Pre-Funded Warrants

In December 2017, the Company filed a shelf registration statement on Form S-3 with the SEC, File No. 333-222366, that became effective January 10, 2018 (the 2018 Registration Statement). The 2018 Registration Statement gave the Company the ability to sell any combination of the securities described in the 2018 Registration Statement in one or more offerings up to an aggregate offering price of $250.0 million. In connection with the filing of the 2018 Registration Statement, the Company entered into a sales agreement that gave the Company the ability to sell shares of its common stock having an aggregate offering price of up to $75.0 million through "at the market offerings" (the 2017 ATM). The 2017 ATM was terminated effective September 6, 2020, and no shares were sold under the 2017 ATM prior to the termination.

In December 2019, the Company sold to various investors an aggregate of 6,287,878 shares of common stock at a public offering price of $16.50 per share, which included the exercise in full by the underwriters of their option to purchase 1,136,363 additional shares of common stock, and pre-funded warrants to purchase 2,424,242 shares of common stock at a public offering price of $16.499 per warrant. The Company received aggregate net proceeds of $134.7 million from the offering and the option exercise, after deducting underwriting discounts and commissions and offering expenses payable by the Company. The pre-funded warrants became immediately exercisable upon issuance at an exercise price of $0.001 per share, but under their terms, the outstanding pre-funded warrants to purchase shares of the Company's common stock generally may not be exercised if the holder's ownership of the Company's common stock would exceed 19.99% following such exercise. The exercise price and number of shares of common stock issuable upon the exercise of the pre-funded warrants (Warrant Shares) are subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described in the pre-funded warrant agreements. Under certain circumstances, the pre-funded warrants may be exercisable on a "cashless" basis. Both the pre-funded warrants and the Warrant Shares are registered securities.

The pre-funded warrants were classified as a component of permanent stockholders' equity within additional paid-in-capital and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants are equity classified because they are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of common shares upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. The Company valued the pre-funded warrants at issuance, concluding their sales price approximated their fair value, and allocated net proceeds from the sale proportionately to the common stock and pre-funded warrants of which $37.5 million was allocated to the pre-funded warrants and recorded as a component of additional paid-in-capital.

In August 2020, the Company filed a shelf registration statement on Form S-3 with the SEC, File No. 333-248469, that became effective on September 4, 2020 (the 2020 Registration Statement). The Company may from time to time sell any combination of the securities described in the 2020 Registration Statement in one or more offerings up to an aggregate offering price of $300.0 million. In connection with the filing of the 2020 Registration Statement, the Company entered into a sales agreement under which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $100.0 million through "at-the-market" offerings (2020 ATM), which shares are included in the $300.0 million of securities registered pursuant to the 2020 Registration Statement. As of September 30, 2020, no shares have been sold under the 2020 Registration Statement.

The Company carried forward registration fees paid with respect to $21.4 million of securities that remained available under the 2018 Registration Statement. As such, as of the effectiveness of the 2020 Registration Statement, the 2018 Registration Statement was deemed terminated.

Common Stock Warrants

The following warrants to purchase shares of the Company's common stock were issued and outstanding:

Issue date	Expiration date	Exercise Price per Share	September 30, 2020	December 31, 2019
September 10, 2010	September 10, 2020	$ 30.000	—	15,296
December 16, 2019	None	$ 0.001	2,424,242	2,424,242
			2,424,242	2,439,538

There were no warrants exercised during the three and nine months ended September 30, 2020 or 2019.

Note 7 – Stock Plans and Stock-Based Compensation

Equity Incentive Plans

In May 2018, the Company's stockholders approved (1) the Assembly Biosciences, Inc. 2018 Stock Incentive Plan (the 2018 Plan) pursuant to which the Company reserved 1,900,000 shares of its common stock for issuance in connection with equity incentive awards and (2) the Assembly Biosciences Inc. Employee Stock Purchase Plan (the 2018 ESPP) pursuant to which the Company reserved 400,000 shares of its common stock for issuance in connection with purchases by employees pursuant to this plan.

In May 2019, the Company's stockholders approved an amendment to the 2018 Plan that increased the aggregate number of shares of common stock reserved under the 2018 Plan to 3,000,000.

In June 2020, the Company's stockholders approved an amendment to the 2018 Plan that increased the aggregate number of shares of common stock reserved under the 2018 Plan to 4,600,000.

As of September 30, 2020, the Company had awards outstanding under the following shareholder-approved plans: 2010 Equity Incentive Plan (the 2010 Plan), which has been frozen; the Amended and Restated 2014 Stock Incentive Plan (the 2014 Plan); and the 2018 Plan. Shares of common stock underlying awards that are forfeited under the 2010 Plan on or after June 2, 2016 will become available for issuance under the 2014 Plan. As of September 30, 2020, the Company also had awards outstanding under the Assembly Biosciences, Inc. 2017 Inducement Award Plan (the 2017 Plan), the Assembly Biosciences, Inc. 2019 Inducement Award Plan (the 2019 Plan) and the Assembly Biosciences, Inc. 2020 Inducement Award Plan (the 2020 Plan).

The Company issues new shares of common stock to settle options exercised and vested RSUs. The Company also issues new shares of common stock in connection with purchases of shares of common stock by eligible employees under the Company's 2018 ESPP.

Stock Plan Activity

Stock Options

A summary of the Company's option activity and related information for the nine months ended September 30, 2020 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2019	5,613,353	$ 15.90		
Granted	1,486,780	16.79		
Exercised	(172,779)	9.78		
Forfeited	(266,436)	21.49		
Outstanding as of September 30, 2020	6,660,918	$ 16.03	7.1	$ 26,951
Options vested and exercisable as of September 30, 2020	3,652,897	$ 14.34	5.6	$ 22,820

The weighted-average grant-date fair value of options granted was $11.01 and $10.79 during the nine months ended September 30, 2020 and 2019, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2020 and 2019 was $2.0 million and $1.6 million, respectively.

RSUs

A summary of the Company's RSUs and related information for the nine months ended September 30, 2020 is as follows:

	Number of RSUs	Weighted Average Fair Value Per RSU at Grant Price
Nonvested as of December 31, 2019	758,718	$ 25.47
Granted	531,164	16.31
Vested	(228,925)	24.73
Forfeited	(69,368)	23.68
Nonvested as of September 30, 2020	991,589 [(1)]	$ 20.86

(1) Includes 140,000 RSUs that have vested but are subject to deferred settlement, which have a weighted average remaining contractual term of 2.4 years.

The total fair value of RSUs vested and settled during the nine months ended September 30, 2020 and 2019 was $6.2 million and $3.6 million, respectively. The total intrinsic value of RSUs vested and settled during the nine months ended September 30, 2020 and 2019 was $3.9 million and $1.8 million, respectively.

As of September 30, 2020, RSUs outstanding include 100,000 RSUs granted in September 2019 to the Company's chief executive officer with performance-based conditions vesting conditions. The 100,000 awards with an aggregate fair value of $1.2 million vest upon performance conditions not yet deemed probable and accordingly no stock-based compensation expense has been recognized as of September 30, 2020. In July 2020, the performance condition for 45,000 RSUs granted in December 2017 to an executive officer was met. The Company recognized $0.7 million as a cumulative catch-up adjustment of stock-based compensation expense for this award for the nine months ended September 30, 2020.

ESPP

Employees purchased 42,266 and 36,804 shares of common stock under the 2018 ESPP during the nine months ended September 30, 2020 and 2019, respectively.

Valuation Assumptions

The fair value of the stock options granted or modified during the periods indicated was estimated using the Black-Scholes option pricing model, based on the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Exercise price	$20.14 - $23.30	$10.91 - $49.14	$14.45 - $23.30	$10.91 - $57.33
Expected volatility	68.9% - 81.6%	66.4% - 80.6%	66.4% - 82.2%	66.2% - 83.2%
Risk-free rate	0.26% - 0.52%	1.36% - 1.89%	0.26% - 1.44%	1.36% - 2.65%
Expected term (years)	5.5 - 7.0	5.5 - 9.6	5.5 - 7.5	5.0 - 9.6
Expected dividend yield	0%	0%	0%	0%

The fair value of RSUs granted is determined based on the price of the Company's common stock on the date of grant.

The fair value of ESPP purchase rights were not material for any period presented.

Stock-Based Compensation Expense

The following table summarizes the components of total stock-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2020	2019	2020	2019	
Research and development	$ 2,759	$ 2,464	$ 8,310	$ 8,309	
General and administrative	3,289	2,940	9,796	5,740	(1)
Total stock-based compensation expense	$ 6,048	$ 5,404	$ 18,106	$ 14,049	

(1) Includes the reversal of previously recognized stock-based compensation expense of $3.6 million related to forfeited awards resulting from the departure of one of the Company's former officers during the period.

As of September 30, 2020, there was $27.8 million of total unrecognized stock-based compensation related to outstanding equity awards which is expected to be recognized over a weighted average remaining amortization period of 1.8 years.

Note 8 - Collaboration Agreements

Allergan Agreement

In January 2017, the Company entered into the Allergan Agreement with Allergan to develop and commercialize select microbiome gastrointestinal disease therapies. The terms and conditions as well as the accounting analysis for the Allergan Agreement are described in Note 8 "Collaboration Agreement" to the consolidated financial statements in the Company's Annual Report on Form 10-K.

In June 2020, following its acquisition of Allergan, AbbVie, on behalf of Allergan, gave written notice of termination of the Allergan Agreement, which subsequently became effective on October 10, 2020. Upon termination, the licenses granted by the Company and its know-how reverted to the Company. Under the terms of the Allergan Agreement, AbbVie is obligated to continue to reimburse the Company for certain research and development costs through October 10, 2020. Upon effectiveness of the termination, such reimbursements will cease. Due to the delivery of the termination notice, the Company determined there were no further enforceable rights and obligations under the Allergan Agreement beyond June 2020 and the remaining $36.0 million of deferred revenue was recognized in the period.

For the three months ended September 30, 2020, the Company recognized $3.6 million in collaboration revenue associated with the Allergan Agreement, none of which had been included in deferred revenue at the beginning of the period. For the nine months ended September 30, 2020, the Company recognized $47.1 million in collaboration revenue associated with the Allergan Agreement, of which $37.0 million was included in deferred revenue as of the beginning of the period. For the three and nine months ended September 30, 2019, the Company recognized $4.2 million and $11.2 million in revenue, respectively, of which $1.2 million and $2.2 million, respectively, had been included in deferred revenue at the beginning of the period. Short-term and long-term deferred revenue contract liabilities related to the Allergan Agreement were $6.4 million and $30.6 million as of December 31, 2019. There were no deferred revenue contract liabilities as of September 30, 2020 due to the Company recognizing a cumulative catch-up adjustment of the remaining deferred revenue balance during the nine months ended September 30, 2020 for the determined completion of the Company's performance obligations under the Allergan Agreement upon receipt of the notice of termination from AbbVie. Contract asset balances of $3.6 million and $3.4 million were recorded as accounts receivable from collaboration on the condensed consolidated balance sheets as of September 30, 2020 and December 31, 2019, respectively.

BeiGene Agreement

In July 2020, the Company and BeiGene entered into the BeiGene Agreement to develop and commercialize the Company's novel core inhibitor product candidates VBR, ABI-H2158 and ABI-H3733 for chronic HBV infection (the Licensed Product Candidates) in the People's Republic of China, Hong Kong, Taiwan and Macau (the Territory). Under the agreement, the Company and BeiGene are collaborating on certain global clinical studies and both the Company and BeiGene will independently conduct other clinical studies in their own respective territories.

BeiGene agreed to pay all development and regulatory costs for the Licensed Product Candidates in the Territory up to an aggregate of $45.0 million. Development and regulatory costs for the Licensed Product Candidates for the Territory in excess of $45.0 million will be shared equally by the Company and BeiGene. If the Company conducts certain ancillary trials outside of the plan to develop these candidates in the Territory, BeiGene may elect to obtain access to the know-how and clinical data resulting for such ancillary trials and shall reimburse the Company proportionally for the Territory of the costs of such trials. Activities under the BeiGene Agreement will be governed by a joint steering committee (JSC) consisting of equal representatives from each party to the agreement. All decisions of the JSC are to be made by consensus with final decision-making authority granted to each party based on key areas of the collaboration for which they are responsible. During the term of the BeiGene Agreement, neither party will commercialize any competing products in the Territory. The Company will be responsible for manufacturing and supply of the candidates to be used in and outside of the Territory, although the parties may approve BeiGene to take on some or all of the commercial supply activities of the applicable Licensed Products in the Territory.

The Company is not obligated to perform pre-phase 3 clinical trial development work outside the Territory on ABI-H2158 and ABI-H3733 but must provide BeiGene pre-Phase 3 clinical trial knowhow and development results if and when such development efforts are completed. If, after ABI-H2158 and ABI-H3733 reach the end of Phase 2 clinical trials, the Company and BeiGene are unable to mutually agree on the terms of a Phase 3 global study, BeiGene may elect to terminate the BeiGene Agreement solely as it relates to that compound, as applicable. Such a termination would result in the Company regaining all rights to the applicable compound in the Territory. In addition, BeiGene may terminate the BeiGene Agreement for convenience at any time upon 90 days' advance written notice to us. The BeiGene Agreement also contains customary provisions for termination by either party, including in the event of breach of the BeiGene Agreement, subject to cure.

Pursuant to the terms of the BeiGene Agreement, the Company received an upfront cash payment of $40.0 million from BeiGene for the delivery of exclusive, royalty-bearing licenses to develop and commercialize the Licensed Product Candidates in the Territory, and the Company is eligible to receive up to approximately $500.0 million in cash milestone payments, comprised of up to $113.8 million for development and regulatory milestones and up to $385.0 million in net sales milestones. In addition, the Company is eligible to receive tiered royalties at percentages ranging from the mid-teens to the low thirties of net sales.

The BeiGene Agreement is within the scope of the collaborative arrangements guidance as both parties are active participants and are exposed to significant risks and rewards dependent on the success of commercializing the Licensed Product Candidates in the Territory but that the unit of account related to the delivery of Licensed Product Candidates is within the scope of the contract with customers guidance. The remaining units of account related to participation on the JSC and subcommittees, clinical supply and other in Territory and global development activities (the Collaboration Activities) are within the scope of the collaborative arrangements guidance. Commercial supply will be evaluated as a separate contract when the agreement is executed and a purchase order is received from BeiGene.

The Company identified the following material promises related to the contract with customers unit of account under the BeiGene Agreement: 1) the transfer of the VBR License, 2) the transfer of the ABI-H2158 License, and 3) the transfer of the ABI-H3733 License. The Company concluded each of these licenses to be functional as they have significant standalone functionality and grants BeiGene the right to use the Company's intellectual property as it exists on the effective date of the license. The ABI-H2158 and ABI-H3733 Licenses have a continuing technology transfer obligation that is considered to be an attribute of these licenses. The agreed upon prices for the clinical and commercial supply of the Licensed Product Candidates to BeiGene do not represent material rights, and therefore are not performance obligations, and such pricing on an aggregate basis represents the standalone selling price an entity would typically pay for such a product in that region or market. There are also no minimum purchase commitments.

The Company estimated the standalone selling price (SSP) of the Licenses using an income-based valuation approach for the estimated value a licensor of the compounds would receive considering the stage of the compound's development. The Company believes a change in the assumptions used to determine its best estimate of SSP would not have a significant value on the allocation of consideration received.

The transaction price at the inception of the agreement was limited to the $40.0 million upfront payment. The variable consideration related to the remaining development and commercialization milestone payments has not been included in the transaction price as these were fully constrained as of September 30, 2020. As part of the Company's evaluation of the development and commercialization milestones constraint, the Company determined the achievement of such milestones are contingent upon success in future clinical trials and regulatory approvals which are not within its control and uncertain at this stage. Any variable consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the Licensed Product Candidates granted to BeiGene. The Company will reevaluate the transaction price in each reporting period as uncertain events are resolved or other changes in circumstances occur.

During the three and nine months ended September 30, 2020, the Company recognized $31.0 million as collaboration revenue for the amount allocated to the VBR License as substantial completion of the license technology transfer has occurred. The remaining transaction price allocated to the ABI-H2158 and ABI-H3733 Licenses of $9.0 million was recorded as a long-term deferred revenue contract liability on the unaudited condensed consolidated balance sheet as of September 30, 2020. Revenue for these performance obligations will be recognized when the Company provides pre-Phase 3 clinical trial know-how and development results for these compounds to BeiGene or a termination of the BeiGene Agreement for the respective compound.

Payments to, or reimbursements from, BeiGene related to the Collaboration Activities will be accounted for as an increase to or reduction of research and development expenses when incurred or realized, respectively. During the three and nine months ended September 30, 2020, the Company did not recognize any increase or reduction of research and development expense under the BeiGene Agreement.

The Company incurred $3.5 million in incremental costs of obtaining the BeiGene Agreement. These contract costs have been capitalized and are being recognized consistent with the pattern of recognition of revenue associated with the Licensed Product Candidates. As of September 30, 2020, $2.7 million has been amortized to general and administrative expenses and $0.8 million is included in other assets on the condensed consolidated balance sheet.

Arbutus Agreement

In August 2020, the Company and Arbutus Biopharma Corporation (Arbutus) entered into a Collaboration Agreement (Arbutus Agreement) to conduct a randomized, multi-center, open-label Phase 2 clinical trial to explore the safety, PK and antiviral activity of the triple combination of VBR, AB-729 and an NrtI compared to the double combinations of VBR with an NrtI and AB-729 with an NrtI. Assembly and Arbutus will share responsibility for the costs of the trial equally, excluding manufacturing supply which will be the burden of each company to supply their respective drugs VBR and AB-729.

The Arbutus Agreement is within the scope of the collaborative arrangements guidance as both parties are active participants and are exposed to significant risks and rewards dependent on the success of the collaborative activity. Arbutus is not a customer as it does not obtain an output from the collaborative activities as they were not provided an exclusive license to VBR or the ability to manufacture VBR, and the Company does not consider performing such collaborative activities to be a part of its ongoing activities.

The revenue from contracts with customers guidance was considered by analogy in determining the unit of account, and the recognition and measurement of such unit of account for collaborative activities under the Arbutus Agreement and concluded there is one activity, to run an open-label Phase 2 clinical trial, which is akin to performance obligation related to collaborative activities. Reimbursements and cost-sharing portions of this performance obligation will be reflected as a reduction of research and development expense when realized in the Company's condensed consolidated statements of operations, as the Company does not consider performing research and development services for reimbursement to be a part of its ongoing major or central operations

Contract Liabilities

The following table presents changes in the Company's contract liabilities (in thousands):

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Nine Months Ended September 30, 2020				
Contract liabilities:				
Deferred revenue	$ 37,048	$ 40,000	$ (68,061)	$ 8,987

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Nine Months Ended September 30, 2019				
Contract liabilities:				
Deferred revenue	$ 40,660	$ —	$ (2,241)	$ 38,419

Note 9 - Milestones and Research Agreements

HBV Research Agreement with Indiana University

Since September 2013, the Company has been party to an exclusive License Agreement dated September 3, 2013 with Indiana University Research and Technology Corporation (IURTC) from whom it has licensed aspects of the Company's HBV program held by IURTC. The license agreement requires the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones. The aggregate amount of all performance milestone payments under the IURTC license agreement, should all milestones through development be met, is $0.8 million, with a portion related to the first performance milestone having been paid. The Company is obligated to pay IURTC royalty payments based on net sales of the licensed technology as well as a portion of any sublicensing revenue Assembly receives. The Company is also required to pay diligence maintenance fees each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than such fees for that year. A performance milestone totaling $0.1 million was determined to have occurred under this agreement and was paid during the three and nine months ended September 30, 2020. Additionally, the Company paid IURTC $0.7 million as a sublicensing fee during the three and nine months ended September 30, 2020. The milestone and license fees are included in research and development expenses in the condensed consolidated statements of operations and comprehensive loss. Amounts paid in the nine months ended September 30, 2019 were insignificant.

Microbiome Targeted Colonic Delivery Platform

In November 2013, the Company entered into a License and Collaboration Agreement with Therabiome, LLC (Therabiome), for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release capsule-in-capsule technology. The Company will be solely responsible for all research and development activities with respect to any product it develops under the license.

The Company must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones. In addition, the Company must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region. The Company is also required to pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed certain thresholds, a one-time cash payment upon reaching such thresholds.

Therabiome must pay the Company royalties on annual net sales of any product Therabiome is permitted to develop using the intellectual property in the low double to mid-double-digit percentages, depending on the level of development or involvement the Company had in the product.

No amounts were accrued for this agreement as of and for the nine months ended September 30, 2020. Two regulatory milestones totaling $0.3 million were determined to have occurred under this agreement and were paid during the nine months ended September 30, 2019.

Note 10 - Leases

Operating Leases

The Company leases office space for corporate, administrative and laboratory functions in South San Francisco, California under a sub-sublease that expires in December 2023. The Company also leases office space in Carmel, Indiana under a lease agreement that expires in August 2023, which the Company has subleased. The Company also leases office and laboratory space in Groton, Connecticut under a lease that expires in March 2021. The Company's China subsidiary leases office space in Shanghai that expires in May 2021 and rents lab space in Shanghai under a lease agreement that expires in December 2020. Additionally, the Company's China subsidiary leases office space in Beijing under a lease agreement that expires in December 2021. Certain lease contracts contain renewal clauses that the Company assesses on a case by case basis. The Company also leases certain laboratory equipment accounted for as operating leases. Certain equipment leases continue to expire in 2020, with the final lease expiring in 2023.

When the Company cannot determine the implicit rate in its leasing arrangements, the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment.

At September 30, 2020, the Company had operating lease liabilities of $10.8 million and ROU assets of $10.4 million, which were included in the condensed consolidated balance sheet.

The following summarizes quantitative information about the Company's operating leases (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Lease cost				
Operating lease cost	$ 1,164	$ 1,136	$ 3,463	$ 3,344
Short-term lease cost	101	88	301	520
Variable lease cost	409	301	1,101	900
Total lease cost	$ 1,674	$ 1,525	$ 4,865	$ 4,764

	Nine Months Ended September 30,	
	2020	2019
Operating cash flows from operating leases	$ 3,382	$ 3,188
ROU assets exchanged for new operating lease liabilities	$ 1,063	$ 15,261

As of September 30, 2020 and December 31, 2019, the weighted-average remaining lease term for operating leases was 3.0 years and 2.7 years, respectively. As of September 30, 2020 and December 31, 2019, the weighted-average discount rate for operating leases was 9.3% and 9.4%, respectively.

As of September 30, 2020, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Three months ending December 31, 2020	$ 1,208
Year Ending December 31, 2021	4,182
Year Ending December 31, 2022	3,818
Year Ending December 31, 2023	3,436
Total	12,644
Less: present value discount	(1,871)
Operating lease liabilities	$ 10,773

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The interim condensed consolidated financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the consolidated financial statements and notes thereto for the year ended December 31, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed with the U.S. Securities and Exchange Commission on March 4, 2020 (2019 Annual Report). In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1A. Risk Factors" in our 2019 Annual Report, "Part II. Item 1A. Risk Factors" in this report, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a clinical-stage biotechnology company developing innovative therapeutics targeting chronic hepatitis B virus (HBV) infection and disorders associated with the microbiome. Our HBV Cure program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. Our Microbiome program is developing novel oral live microbial biotherapeutic candidates with our fully integrated platform, including a robust process for strain identification and selection, current Good Manufacturing Practice (cGMP) manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology.

Like most companies, the spread of the novel coronavirus, SARS-CoV-2, which causes coronavirus disease (COVID-19), and the ongoing COVID-19 pandemic has affected certain aspects of our business. As further detailed below, those effects have been primarily limited to where and how our employees work in our labs and offices. To date, our current and future planned clinical trials and pre-clinical studies have not been subject to significant impact as a result of the COVID-19 pandemic.

Business Highlights

During the third quarter of 2020, we continued to grow our business and advance our development pipeline of product candidates in both our HBV Cure and Microbiome programs. Key highlights and accomplishments during the quarter, as well as upcoming milestones and subsequent events include:

HBV Cure Program

- Vebicorvir (VBR or ABI-H0731 (H0731)), our lead core inhibitor product candidate in the HBV Cure program:

  - Continuation of our ongoing open-label extension study, ABI-H0731-211 (Study 211), and transition of patients who achieve agreed-upon stopping criteria off therapy. Study 211 is the first clinical trial with a core inhibitor to stop therapy and monitor for sustained virologic response (SVR) in patients with chronic HBV infection. Patients who stopped therapy in Study 211 have not achieved meaningful SVR rates as 39 of 41 patients have now relapsed. We continue to collect and analyze Study 211 data and intend to submit more detailed findings to a future medical meeting.

  - Presentation of additional interim analyses on HBeAg positive and negative patients from Study 211 at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress™.

  - Continuation of a study, ABI-H0731-205, evaluating treatment intensification with VBR in patients with chronic HBV infection who are only partially virologically suppressed on nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) therapy alone after at least a year of treatment.

  - End-of-Phase 2 Meeting with National Medical Products Administration, Center for Drug Evaluation, China, in July 2020 with agreement on Phase 3 registrational program for chronic suppressive therapy.

- ABI-H2158 (H2158), our second-generation core inhibitor product candidate in the HBV Cure program:
  - Continuation of a Phase 2 clinical study, ABI-H2158-201, using a 300 mg dose of H2158.
  - Presentation of detailed data on the final dose-ranging cohorts of the Phase 1b portion of the Phase 1a/1b clinical study of H2158 at EASL 2020.
- ABI-H3733 (H3733), our third core inhibitor product candidate in the HBV Cure program:
  - Continuation of a Phase 1 clinical study, ABI-H3733-101, to evaluate safety, tolerability, and pharmacokinetics (PK) of H3733 in healthy subjects.
- Upcoming HBV presentations at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting (The Liver Meeting®), November 13 to 16, 2020:
  - "Analysis of the longer-term safety profile of the hepatitis B virus core inhibitor ABI-H0731 in an open-label extension study";
  - "Persistently detectable serum HBV pgRNA is associated with subsequent hepatocellular carcinoma development in chronic HBV patients receiving chronic NrtI treatment";
  - "Amino acid substitutions in the inhibitor binding pocket of HBV core protein confer differential changes in susceptibility to three generations of HBV core inhibitors"; and
  - "Changes in viral antigens are more strongly associated with HBV pgRNA than HBV DNA in studies of VBR and NrtI in treatment-naïve patients with chronic HBV infection."
- Triple Combination HBV Studies:
  - Entry into a Clinical Trial Collaboration Agreement (Triple Combination Collaboration Agreement) with Arbutus to evaluate VBR in combination with Arbutus' proprietary GalNAc delivered RNAi compound AB-729 and NrtI therapy for the treatment of patients with chronic HBV infection.
  - Initiation of a Phase 2 triple combination study evaluating the addition of interferon to VBR and NrtI expected in the first half of 2021.

Microbiome Program

- Continuation of process identifying strategic alternatives to continue development of the Microbiome programs following the return of rights to such programs from Allergan Pharmaceuticals International Limited (Allergan) upon termination of the Research, Development, Collaboration and License Agreement (Allergan Agreement).

Corporate Highlights

- Appointment of Gina Consylman to our Board of Directors (the Board) and the Board's Audit Committee.

HBV Cure Program

Over 250 million people worldwide are chronically infected with HBV. Our HBV Cure program is pursuing multiple drug candidates that inhibit the HBV lifecycle and block the generation of covalently closed circular DNA (cccDNA), with the aim of increasing the current low cure rate for patients with HBV. We have discovered several novel core inhibitors, which are small molecules that directly target and allosterically modulate the HBV core protein.

Vebicorvir

VBR, our lead core inhibitor product candidate in the HBV Cure program, is licensed from Indiana University. The conduct of the Phase 2 studies, Study 201 and 202, is now complete, and our open-label extension study, Study 211, is ongoing. We continue to present interim updates on our clinical studies at conferences, including EASL 2020 in August 2020 and AASLD 2020 in November 2020.

The stopping criteria for transitioning patients off therapy in Study 211 were discussed with our lead investigators and reviewed and agreed upon by the FDA. All patients who met the stopping criteria are off treatment and being observed for SVR. Patients who stopped therapy in Study 211 have not achieved meaningful SVR rates as 39 of 41 patients have now relapsed. We continue to collect and analyze Study 211 data and intend to submit more detailed findings to a future medical meeting.

When enrolled patients are unable to come to the clinic as a result of the COVID-19 pandemic, study drug is shipped to their homes, and sites conduct telehealth visits. All currently enrolled patients are continuing with normal study visits, and we continue to monitor for a potential impact of the COVID-19 pandemic on the study.

ABI-H2158

H2158, our second-generation core inhibitor product candidate in the HBV Cure program, was internally discovered and developed and is chemically distinct from VBR.

We reported the final data from dose-ranging cohorts of the Phase 1b portion of the Phase 1a/1b dose-ranging clinical study at EASL 2020. Based on data from the Phase 1b dose-ranging study, we initiated a Phase 2 clinical study in June 2020 using a 300 mg dose of H2158. This study will be conducted in approximately ten countries in Asia, North America and Europe. While we will continue to monitor the situation closely, at this time, we do not expect our timelines for this study to be significantly impacted by the COVID-19 pandemic.

ABI-H3733

H3733, our third core inhibitor product candidate in the HBV Cure program, has completed Investigational New Drug (IND) enabling studies. H3733 has a novel chemical scaffold separate from both H0731 and H2158. We presented a preclinical profile of this candidate in the first quarter of 2019.

In the first quarter of 2020, we initiated a Phase 1 clinical study to evaluate safety, tolerability and PK following single ascending dose and multiple ascending dose administration of H3733 in healthy subjects in New Zealand. After a short delay in enrollment of the study due to the government-mandated shutdown of all clinical studies unrelated to COVID-19, we resumed enrollment during the second quarter of this year. This delay did not have a significant impact on our clinical development timelines for H3733.

Other Product Candidates

In addition to our three clinical-stage product candidates, our research discovery team is actively focused on identifying and developing additional product candidates for our HBV Cure program.

Collaboration Agreements

China HBV Collaboration Agreement

In July 2020, we entered into a Collaboration Agreement with BeiGene, granting BeiGene an exclusive, royalty-bearing license to develop and commercialize products containing VBR, H2158 and H3733 (the BeiGene Agreement) in the People’s Republic of China, Hong Kong, Taiwan and Macau (the Territory).

Under the BeiGene Agreement, we and BeiGene will collaborate on development activities with respect to the licensed products in accordance with a mutually agreed upon development plan. A registrational study is expected to initiate in the first half of 2021 and will initially focus on vebicorvir in combination with NrtI as chronic suppressive therapy.

Pursuant to the terms of the BeiGene Agreement, BeiGene paid us an upfront amount of $40.0 million, and we are eligible to receive up to approximately $500.0 million in milestone payments, comprised of up to $113.8 million in development and regulatory and $385.0 million in net sales milestone payments. In addition, we are eligible to receive tiered royalties at percentages ranging from the mid-teens to the low 30s of net sales. BeiGene has also agreed to pay all development and regulatory costs up to an aggregate of $45.0 million in the territory for VBR, H2158 and H3733. Following this initial investment, we and BeiGene will share development costs for the Territory equally.

The BeiGene Agreement also contains provisions such as representations and warranties of the parties, terms as to governance of the collaboration, commercialization and regulatory responsibilities of the parties, and manufacturing and supply, including potential adjustments in the event supply costs exceed certain levels. In addition, during the term of the BeiGene Agreement, neither party will commercialize any competing products in the Territory.

If, after H2158 and H3733 reach the end of Phase 2 clinical trials, we and BeiGene are unable to mutually agree on the terms of a Phase 3 global study, BeiGene may elect to terminate the BeiGene Agreement solely as it relates to that compound, as applicable. Such a termination would result in us regaining all rights to the applicable compound in the Territory. In addition, BeiGene may terminate the BeiGene Agreement for convenience at any time upon 90 days' advance written notice to us. The BeiGene Agreement also contains customary provisions for termination by either party, including in the event of breach of the BeiGene Agreement, subject to cure.

Triple Combination HBV Collaboration

In August 2020, we entered into the Triple Combination Collaboration Agreement, pursuant to which we and Arbutus will conduct a randomized, multi-center, open-label Phase 2 clinical trial to explore the safety, PK and antiviral activity of the triple combination of VBR, AB-729 and an NrtI compared to the double combinations of VBR with an NrtI and AB-729 with an NrtI. This clinical trial is projected to initiate in the first half of 2021 and enroll approximately 60 virologically suppressed patients with HBeAg negative or positive chronic HBV infection.

Microbiome Program

In recent years, there has been increasing scientific evidence suggesting the therapeutic potential of the human microbiome—the billions of microbes living in and on people—to impact health and disease. Our Microbiome program builds upon experience reported in the literature of successfully treating various disease indications with fecal microbiota transplants and seeks to provide a pharmacologically relevant therapy using a "drug like" approach that delivers targeted and specific microbiome therapies in an oral capsule.

Our Microbiome program consists of a fully integrated platform that includes a biological-function-based strain isolation, identification, characterization and selection process, methods for strain purification and growth under conditions compliant with cGMP requirements, and a licensed patented delivery system, GEMICEL®, which is designed to allow for targeted oral delivery of live biologic and conventional therapies to the lower GI tract.

ABI-M201

Our Microbiome program's lead candidate, M201, is in a multi-center, randomized, double-blind, placebo-controlled Phase 1b clinical trial to evaluate its safety and efficacy in patients with mildly to moderately active ulcerative colitis (UC) who are being treated with mesalamine. The study's primary objective is safety and tolerability, and its secondary objectives focus on the effect of M201 treatment on disease activity measures in patients with UC.

This Phase 1b study is ongoing. Enrollment had been delayed due to the COVID-19 pandemic and the limitations placed on some trial sites to conduct certain procedures as part of the patient screening process. Enrollment has resumed, and we continue to monitor the situation closely. When enrolled patients are unable to come to the clinic, study drug or placebo is shipped to their homes and sites are conducting telehealth monitoring and home health nurse visits. Preclinical data from the M201 program was selected for presentation as a poster at Digestive Disease Week (DDW) in May 2020; however, DDW 2020 was cancelled due to the COVID-19 pandemic.

M201 was initially developed as part of the Allergan Agreement, which provided for the development and commercialization of microbiome gastrointestinal programs. While we explore strategic alternatives for continued development of our Microbiome programs, the Phase 1b study of M201 will continue despite the termination of the Allergan Agreement. See "—Allergan Agreement."

Additional Product Candidates

Using our microbiome platform capabilities, we are also exploring additional product candidates for other disease indications, including Crohn's disease and irritable bowel syndrome in connection with the Allergan Agreement, as well as immune-mediated and metabolic disorders and oncology, which indications we will pursue either internally or in collaboration with other third parties. Preclinical data from our immuno-oncology microbiome program was presented as an e-poster at AACR in June 2020.

Allergan Agreement

In May 2020, AbbVie Inc. (AbbVie) completed its acquisition of Allergan. In June 2020, AbbVie notified us that it decided to terminate the Allergan Agreement. This decision was not based on any efficacy, safety or other data related to collaboration programs. On October 10, 2020, the termination became effective, and we regained worldwide rights to all microbiome candidates subject to the collaboration, including M201. We have begun exploring strategic alternatives to continue development of the Microbiome programs following the return of the related intellectual property rights.

Operations

We currently have corporate and administrative offices and research laboratory space in South San Francisco, California and research, development and small-scale manufacturing activities in Groton, Connecticut. We also currently have an administrative office and research laboratory space in Shanghai, China and a regulatory office in Beijing, China.

Since our inception, we have had no revenue from product sales and have funded our operations principally through equity financings and collaborations. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, discovering and developing our product candidates, establishing small-scale manufacturing capabilities for certain of our product candidates, maintaining and improving our patent portfolio and raising capital.

We have generated significant losses to date, and we expect to continue to generate losses as we continue to develop our product candidates. As of September 30, 2020, we had an accumulated deficit of $462.2 million. Because we do not generate revenue from any of our product candidates, our losses will continue as we further develop, seek regulatory approval for and commercialize our product candidates. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none are approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

In mid-March 2020, as a result of the COVID-19 pandemic, six San Francisco Bay Area counties announced a shelter-in-place order, restricting all residents to their homes, with few exceptions. Within a week, both California and Connecticut issued state-wide stay-at-home orders. As a biotechnology company, we were exempt from such orders. California's state-wide and local orders remain in place. Connecticut's order expired in May 2020.

Because of the exemptions described above, there has not been any significant interruption to date of essential activities at our offices, including work in our laboratories in both South San Francisco and Groton with proper protections and procedures in place. While we have experienced some shipping delays or shortages of personal protective equipment (PPE) that are important to maintaining normal workflows in our laboratories, we have been able to continue our critical research activities through schedule shifts, use of PPE on-hand and reallocation of certain resources that allow our employees to practice "social distancing" and comply with applicable laws. Notwithstanding the expiration of Connecticut's stay-at-home order, substantially all of our U.S.-based non-research employees at both our South San Francisco and Groton facilities have been working from their homes since mid-March 2020. Clinical study-related impacts of the COVID-19 pandemic to date have been limited to short enrollment delays for our Phase 1 study of H3733 and our Phase 1b study of M201. We cannot currently predict the specific extent, duration or full impact that the COVID-19 pandemic will have on our ongoing and planned research efforts, clinical trials and other business operations. We continue to monitor the situation regularly for additional potential delays, or modifications to our ongoing and planned trials and, if circumstances warrant, we may adjust our budget and operating plan.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our condensed consolidated financial statements, which have been prepared in accordance with the accounting principles generally accepted in the United States (U.S. GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, and expenses.

We evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation, on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting policies and significant estimates are detailed in our 2019 Annual Report. Our critical accounting policies and significant estimates have not changed from those previously disclosed in our 2019 Annual Report, except for those accounting subjects discussed in the section of Note 2 to the unaudited condensed consolidated financial statements titled Adoption of Recent Accounting Pronouncements included in this Quarterly Report on Form 10-Q.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

Collaboration Revenue

The following table summarizes the period-over-period changes in our collaboration revenue (in thousands, except for percentages):

	Three Months Ended September 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
Collaboration revenue	$ 34,611	$ 4,231	$ 30,380	718%

Collaboration revenue for the three months ended September 30, 2020 includes the recognition of $31.0 million recognized for the transfer of the VBR License upon entering into the BeiGene Agreement as well as reimbursements incurred under the Allergan Agreement.

Research and Development Expense

The following table summarizes the period-over-period changes in our research and development expenses (in thousands, except for percentages):

	Three Months Ended September 30,		$ Change	% Change
Program/Description	2020	2019	2020 vs. 2019	2020 vs. 2019
HBV Cure program	$ 18,700	$ 14,735	$ 3,965	27%
Microbiome program (1)	8,241	7,001	1,240	18%
Total research and development expenses	$ 26,941	$ 21,736	$ 5,205	24%

(1) Expenses presented for the Microbiome program exclude collaboration revenue related to expense reimbursements under the Allergan Agreement as discussed in Note 8 to the Condensed Consolidated Financial Statements.

Research and development expenses were $26.9 million for the three months ended September 30, 2020 compared to $21.7 million for the same period in 2019. The increase was due to an increase of $4.0 million in research and development expenses related to the HBV Cure program and an increase of $1.2 million in research and development expenses related to the Microbiome program. These increases were primarily due to increases in clinical activities, chemistry and manufacturing control activities to support VBR, 2158, 3733 and microbiome clinical trials and increased salary and benefits due to additional employees. Research and development expenses include non-cash stock-based compensation expenses of $2.8 million for the three months ended September 30, 2020 and $2.5 million for the same period in 2019.

General and Administrative Expense

The following table summarizes the period-over-period changes in our general and administrative expenses (in thousands, except for percentages):

	Three Months Ended September 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
General and administrative expenses	$ 11,689	$ 8,488	$ 3,201	38%

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services, accounting and tax services, insurance and travel expenses, as well as stock-based compensation expense associated with equity awards to our employees, consultants, and directors.

General and administrative expenses were $11.7 million for the three months ended September 30, 2020 compared to $8.5 million for the same period in 2019. The increase was primarily due to an increase of $2.7 million in professional fees due to the amortized incremental contract costs associated with entering into the BeiGene Agreement, $0.3 million in equipment rental, $0.4 million in stock-based compensation expense and $0.1 million in salary and benefits due to additional employees. These increases were partially offset by a decrease of $0.2 million in travel related expenses due to state and local laws restricting travel in response to the COVID-19 pandemic. General and administrative expenses include non-cash stock-based compensation expenses of $3.3 million for the three months ended September 30, 2020 and $2.9 million for the same period in 2019.

Comparison of the Nine Months Ended September 30, 2020 and 2019

Collaboration Revenue

The following table summarizes the period-over-period changes in our collaboration revenue (in thousands, except for percentages):

	Nine Months Ended September 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
Collaboration revenue	$ 78,068	$ 11,197	$ 66,871	597%

Collaboration revenue for the nine months ended September 30, 2020 includes the recognition of $31.0 million recognized for the transfer of the VBR License upon entering into the BeiGene Agreement. It also includes the remaining deferred revenue balance and reimbursements incurred under the Allergan Agreement, for which AbbVie (formerly Allergan pre-acquisition) gave written notice of termination in June 2020.

Research and Development Expense

The following table summarizes the period-over-period changes in our research and development expenses (in thousands, except for percentages):

	Nine Months Ended September 30,		$ Change	% Change
Program/Description	2020	2019	2020 vs. 2019	2020 vs. 2019
HBV Cure program	$ 50,337	$ 42,589	$ 7,748	18%
Microbiome program (1)	22,977	20,552	2,425	12%
Total research and development expenses	$ 73,314	$ 63,141	$ 10,173	16%

(1) Expenses presented for the Microbiome program exclude collaboration revenue related to expense reimbursements under the Allergan Agreement as discussed in Note 8 to the Condensed Consolidated Financial Statements.

Research and development expenses were $73.3 million for the nine months ended September 30, 2020 compared to $63.1 million for the same period in 2019. The increase was due to an increase of $7.7 million in research and development expenses related to the HBV Cure program and an increase of $2.4 million in research and development expenses related to the Microbiome program. These increases were primarily due to increases in clinical activities, chemistry and manufacturing control activities to support VBR, 2158, 3733 and microbiome clinical trials and increased salary and benefits due to additional employees. Research and development expenses include non-cash stock-based compensation expenses of $8.3 million for both the nine months ended September 30, 2020 and 2019.

General and Administrative Expense

The following table summarizes the period-over-period changes in our general and administrative expenses (in thousands, except for percentages):

	Nine Months Ended September 30,		$ Change	% Change
	2020	2019	2020 vs. 2019	2020 vs. 2019
General and administrative expenses	$ 29,888	$ 22,085	$ 7,803	35%

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services, accounting and tax services, insurance and travel expenses, as well as the stock-based compensation expense associated with equity awards to our employees, consultants, and directors.

General and administrative expenses were $29.9 million for the nine months ended September 30, 2020 compared to $22.1 million for the same period in 2019. The increase was primarily driven by an increase of $2.7 million in professional fees due to the amortized incremental contract costs associated with entering into the BeiGene Agreement, $1.3 million in salary and benefits, $4.1 million in stock-based compensation expense, $0.4 million in equipment rental and $0.1 million in recruitment expenses due to additional employees partially offset by a decrease of $0.7 million in travel related expenses due to state and local laws restricting travel in response to the COVID-19 pandemic. General and administrative expenses include non-cash stock-based compensation expenses of $9.8 million for the nine months ended September 30, 2020 and $5.7 million for the same period in 2019. Stock-based compensation expense for the nine months ended September 30, 2019 includes the reversal of previously recognized expense of $3.6 million related to forfeited awards resulting from the departure of one of the Company's former officers during the period.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through September 30, 2020 principally through equity financings, raising an aggregate of $546.4 million in net proceeds, and strategic collaborations, raising an aggregate of $90.0 million through upfront payments.

Cash Flows for the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our cash flow activities (in thousands):

	Nine Months Ended September 30,	
Cash provided by (used in):	2020	2019
Operating activities	$ (37,688)	$ (63,539)
Investing activities	47,355	44,704
Financing activities	$ 1,912	$ 2,231

Net Cash from Operating Activities

Net cash used in operating activities was $37.7 million for the nine months ended September 30, 2020. This was primarily due to a $22.7 million net loss, $0.1 million of accretion of discount of marketable securities and a decrease of $36.8 million of operating assets and liabilities, which includes the recognition of the remaining deferred revenue balance of $36.0 million as revenue during the nine months ended September 30, 2020 in connection with AbbVie's decision to terminate the Allergan Agreement as discussed in Note 8. These decreases were partially offset by $18.1 million non-cash expense recorded for stock-based compensation, $3.5 million of amortization of operating lease right-of-use (ROU) assets and $0.4 million of depreciation and amortization expense.

Net cash used in operating activities was $63.5 million for the nine months ended September 30, 2019. This was primarily due to a $70.6 million net loss, $1.5 million of accretion of discount of marketable securities and a decrease of $9.3 million of operating assets and liabilities, which were offset by $14.0 million non-cash expense recorded for stock-based compensation, $3.3 million of amortization of operating lease ROU assets and $0.4 million of depreciation and amortization expense.

Net Cash from Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2020 was $47.4 million due to $165.3 million of redemptions of marketable securities and $35.6 million of sale of marketable securities, which were partially offset by the purchase of $153.0 million of marketable securities and $0.5 million of property and equipment.

Net cash provided by investing activities for the nine months ended September 30, 2019 was $44.7 million primarily due to $166.9 million of redemptions of marketable securities and $28.7 million of sale of marketable securities, which were partially offset by the purchase of $149.3 million of marketable securities and $1.5 million of property and equipment.

Net Cash from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2020 was $1.9 million resulting from the exercise of stock options to purchase 172,779 shares of common stock and the issuance of 42,266 shares of common stock under our ESPP.

Net cash provided by financing activities for the nine months ended September 30, 2019 was $2.2 million resulting from the exercise of stock options to purchase 243,481 shares of common stock and the issuance of 36,804 shares of common stock under our ESPP.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research, development and clinical studies of our product candidates and pursue our intellectual property strategy. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We monitor our cash needs and the status of the capital markets on a continuous basis. From time to time, we opportunistically raise capital and have done so numerous times by issuing equity securities, most recently in December 2019. We intend to continue to raise capital when and as needed and at the time and in the manner most advantageous to us. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and when needed.

We expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. Our future capital requirements will depend on many factors, including:

- the scope, progress, timing, results and costs of our ongoing drug discovery, nonclinical development, laboratory testing and clinical studies of our product candidates and any additional clinical studies we may conduct in the future;
- the extent to which we further acquire or in-license other product candidates and technologies;
- our ability to manufacture, and to contract with third parties to manufacture, adequate supplies of our product candidates for our clinical studies and any eventual commercialization;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of recruiting additional employees to support the growth of our business;
- the costs of preparing, filing and prosecuting patent applications in the United States and abroad, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- our ability to establish and maintain collaborations on favorable terms, if at all.

Identifying potential product candidates and conducting nonclinical testing and clinical studies is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of therapeutics that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financings to achieve our business objectives. Adequate additional financings may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

There were no material changes in our commitments under contractual obligations as disclosed in our 2019 Annual Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes to our quantitative and qualitative disclosures about market risk as compared to the quantitative and qualitative disclosures about market risk described in our 2019 Annual Report.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that is designed to provide reasonable assurance that information that is required to be disclosed in our reports filed pursuant to the Exchange Act, is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rules 13a-15(b) and 15d-15(b) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting in the quarter ended September 30, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceedings. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors

This report contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this report and in any documents incorporated in this report by reference.

You should carefully consider the following risk factors, together with all other information in this report, including our consolidated financial statements and notes thereto, and in our other filings with the Securities and Exchange Commission. If any of the following risks, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Business

We have no approved products and currently are dependent on the future success of our HBV Cure and Microbiome programs.

To date, we have no approved products on the market and have generated no product revenues. Our prospects are substantially dependent on our ability to develop and commercialize our HBV and microbiome product candidates. Unless and until we receive approval from the FDA or other regulatory authorities for our product candidates, we cannot sell our product candidates and will not have product revenues. We will have to fund all of our operations and capital expenditures from cash on hand, any future securities offerings or debt financings and any fees we may generate from out-licensing, collaborations or other strategic arrangements. If we are unable to develop and commercialize any product candidates from our HBV Cure and Microbiome programs, we will be unable to generate revenues from the sale of products or build a sustainable or profitable business.

In addition, all of our product candidates are currently in clinical development or in varying stages of nonclinical development and their risk of failure is high. The data supporting our drug discovery and nonclinical and clinical development programs are derived from either laboratory, nonclinical studies, Phase 1 and Phase 2 clinical data. With respect to our ongoing Phase 2 trials, with patients transitioned off of therapy in Study 211, we may not observe sustained virologic response and such patients may need to resume NrtI therapy. In addition, there is no guarantee that Phase 3 clinical studies, if and when completed, will result in data consistent with that observed in prior studies. As a result, we cannot predict when or if any one of our product candidates will prove safe and effective in humans or will receive regulatory approval.

The scientific evidence to support the feasibility of our product candidates and therapeutic approaches is limited, and many companies, some with more resources than we have, are and may be developing competitive product candidates.

For these and other reasons, our drug discovery and development may not be successful, and we may be unable to continue clinical development of our programs and may not generate product approvals or product revenue. If any of those occur, it will have a material adverse impact on our business, results of operations, financial condition and share price.

The spread of the coronavirus and resulting COVID-19 pandemic may materially and adversely affect our business.

The COVID-19 outbreak began in December 2019 and has since spread globally, reaching pandemic status. The continued spread of COVID-19 could adversely impact our research and development through delay, modification or suspension of our clinical and/or nonclinical studies. Other clinical-stage biotechnology companies, like us, have already had their clinical and nonclinical studies affected by the COVID-19 pandemic.

The COVID-19 pandemic has and may continue to: (1) impact patient enrollment, retention or compliance with clinical study protocols; (2) require modifications to or deviations from study protocols and procedures, such as the use of telehealth and home health visits instead of on-site monitoring and treatment, that could increase the cost of conducting clinical studies; (3) disrupt or suspend the business operations of our third-party contract research organizations (CROs), manufacturers of our drug candidates and the clinical sites conducting our clinical studies; (4) delay regulatory meetings and filings with regulatory agencies in the United States and other countries; and (5) disrupt supply chains and cause delays of shipments of critical reagents, PPE and disinfectants, each of which are necessary for our laboratories and the laboratories of our CROs to maintain normal workflows.

We cannot provide any assurances about when any of our clinical studies that have delayed or may in the future delay enrollment as a result of COVID-19 might reinitiate enrollment or that their enrollment will be reinitiated at all. For those clinical studies that are currently ongoing, we cannot provide any assurances that the measures that we have taken to date, or may in the future take, will continue to allow us to mitigate and manage results of negative impacts to site initiation, participant recruitment and enrollment, participant randomization and dosing, distribution of clinical study materials, study monitoring or data analysis. Even if we are able to collect clinical data while the outbreak is ongoing, COVID-19 may negatively affect the quality, completeness, integrity, interpretability and cost of obtaining such clinical study data. Any of these effects could adversely affect our ability to advance our product candidates in the manner and on the timelines presently planned, obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our business, results of operations, financial results and our share price.

As a result of the COVID-19 pandemic, governments around the world implemented significant measures to control the spread of the virus, including quarantines, travel restrictions, stay-at-home orders and business shutdowns. While governments have been in various stages of relaxing these measures, recent surges in COVID-19 cases, including in Europe and the United States, have prompted some governments to reimplement these restrictions. We continue to take precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees who are able to do so to work remotely and suspending all non-essential business travel worldwide for our employees. These measures could negatively affect our business. For instance, requiring all employees to work remotely may disrupt our operations or increase the risk of a cybersecurity incident.

The extent to which the COVID-19 pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and severity of the pandemic, and the effectiveness of actions for containment and treatment of COVID-19. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, including to our ongoing and planned clinical studies. Any such shutdowns or other business interruptions could result in material and negative effects to our ability to conduct our business in the manner and on the timelines presently planned as well as negatively affect the accuracy of our estimates regarding capital requirements and needs for additional financing or our ability to produce accurate and timely financial statements. We may incur additional liabilities related to business disruptions caused by the COVID-19 pandemic, including those related to our employees, our agreements with third parties, and our interactions with governmental authorities. Any of these disruptions could have a material adverse impact on our business, results of operation, financial condition and share price.

The COVID-19 pandemic has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all. In addition, a recession, depression, or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

In addition to the risks related to the COVID-19 pandemic discussed above, the uncertainty surrounding, and risks created by, the pandemic may have the effect of heightening many of the other risks discussed in this section impacting our operations.

We depend entirely on the success of product candidates from our HBV Cure program and our Microbiome program. We cannot be certain that we or our collaborators will be able to obtain regulatory approval for, or successfully commercialize, product candidates from either of our current programs or any other product candidates we may subsequently identify.

We and our collaborators are not permitted to market or promote any product candidates in the United States, Europe, China or other countries before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for our current product candidates. We have not submitted a biologic license application (BLA) or new drug application (NDA) to the FDA or comparable applications to other regulatory authorities and do not expect to be in a position to do so in the foreseeable future.

All of our product candidates are currently in clinical development or in varying stages of nonclinical development. It may be years before the larger, pivotal trials necessary to support regulatory approval of our product candidates are completed, if ever. The clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must successfully meet a number of critical developmental milestones, including:

- developing dosages that will be tolerated, safe and effective;
- reaching agreement with the FDA or comparable foreign regulatory authorities regarding the scope, design and data necessary to support regulatory approval for the product candidate;
- demonstrating through clinical studies that the product candidate is safe and effective in patients for the intended indication;
- determining the appropriate delivery mechanism;
- demonstrating that the product candidate formulation will be stable for commercially reasonable time periods; and
- completing the development and scale-up to permit manufacture of our product candidates in quantities sufficient to execute on our clinical development plans and, eventually, in commercial quantities with sufficient quality and at acceptable prices.

The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for our HBV and microbiome therapies or any other product candidates that we may develop. We have not yet completed and may never complete the development of any products. If we are unable to complete clinical development of our HBV or microbiome therapies, or any other product candidates that we may identify, we will be unable to generate revenue from the sale of products or build a sustainable or profitable business.

Nonclinical and clinical testing required for our product candidates is expensive and time-consuming and may result in delays or may fail to demonstrate safety and efficacy for desired indications. Such delays or failures could delay or prevent our receipt of licensing, sales and/or milestone revenue.

Before we or any commercial partners can obtain FDA approval (or other foreign approvals) necessary to sell any of our product candidates, we must show through nonclinical studies and human testing in clinical studies that each potential product is safe and effective in humans. To meet these requirements, we must conduct extensive nonclinical testing and sufficient and well-controlled clinical studies. Conducting clinical studies is a lengthy, time consuming, and expensive process. The length of time might vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with product candidates for which we are directly conducting nonclinical studies or clinical studies might cause us to incur additional operating expenses. The commencement and rate of completion of clinical studies might be delayed by many factors, including, for example:

- delays in reaching agreement with regulatory authorities on trial design;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical study sites;
- failure to demonstrate efficacy;
- the emergence of unforeseen safety issues;
- insufficient quantities of qualified materials under cGMP for use in clinical studies due to manufacturing challenges, delays or due to interruption in the supply chain due to shipment delays or custom holds;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of eligible patients, which may be due to a number of reasons, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, and other potential drug candidates being studied;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to product side effects, disease progression or other reasons;
- clinical sites dropping out of a trial to the detriment of enrollment;
- modification of clinical study protocols;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements for clinical studies;
- impacts in trial initiation, enrollment, completion and similar activities due to the impact of COVID-19;
- delays, suspension, or termination of clinical studies by the institutional review board or ethics committee responsible for overseeing the study at a particular study site; and
- government or other regulatory agency delays or clinical holds requiring suspension or termination of our clinical studies.

We have used and intend to continue to rely on one or more CROs to conduct our nonclinical studies and clinical studies. We are highly dependent on these CROs to conduct our studies and trials in accordance with the requirements of the FDA, applicable local laws and good clinical and scientific practice. In the event the CROs fail to perform their duties in such a fashion, we may not be able to complete our clinical studies and may fail to obtain regulatory approval for any of our product candidates.

The failure of nonclinical studies and clinical studies to demonstrate safety and effectiveness of a product candidate for the desired indications could harm the development of that product candidate or other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our nonclinical studies or clinical studies would delay the filing of our NDAs or BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical studies could materially harm our business, financial condition, and results of operations.

Top-line or initial data may not accurately reflect the complete results of a particular study or trial.

We may publicly disclose top-line or initial data from time to time, which is based on a preliminary analysis of then-available efficacy, tolerability, PK and safety data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimates, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate fully and carefully all data. As a result, the top-line or initial results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the initial or preliminary data we previously published. As a result, top-line and initial data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular drug candidate or biotherapeutic and our company in general. In addition, the information we may publicly disclose regarding a particular nonclinical or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the top-line or initial data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed or delayed, which could harm our business, financial condition, operating results or prospects.

We will need to either establish our own clinical and commercial manufacturing capabilities or rely on third parties to formulate and manufacture our product candidates. We rely on third parties to manufacture products that we study in combination with our product candidates. Our use of third parties to manufacture these materials may increase the risk that we will not have sufficient quantities of our product candidates or other products, or necessary quantities of such materials on time or at an acceptable cost.

We currently rely on third-party manufacturers to supply the quantities of VBR, H2158 and H3733 used in our clinical and nonclinical studies and the drug substance for our Microbiome program. We currently manufacture our microbiome drug product for use in our planned nonclinical studies and early-stage clinical studies; however, we may require third-party manufacturers for subsequent clinical studies or other microbiome drug products. In addition, if any product candidate we might develop or acquire in the future receives FDA or other regulatory approval, we will need to either manufacture commercial quantities of the product on our own or rely on one or more third-party contractors to manufacture our products. The establishment of internal manufacturing capabilities is difficult and costly, and we may not be successful in doing so. If, for any reason, we are unable to establish our own manufacturing capabilities and we are unable to rely on any third-party sources we have identified to manufacture our product candidates, either for clinical studies or, at some future date, for commercial quantities, then we would need to identify and contract with additional or replacement third-party manufacturers to manufacture compounds, drug substance and drug products for nonclinical, clinical and commercial purposes. We

might not be successful in identifying additional or replacement third-party manufacturers, or in negotiating acceptable terms with any that we do identify. If we are unable to establish and maintain manufacturing capacity either on our own or through third parties, the development and sales of our products and our financial performance will be materially and adversely affected.

In addition, before we or any of our collaborators can begin to commercially manufacture our product candidates, each manufacturing facility and process is subject to regulatory review. Manufacturing of drugs for clinical and commercial purposes must comply with FDA and applicable non-U.S. regulatory requirements, including cGMPs. The cGMP requirements govern compliance and documentation policies and procedures. Complying with FDA and non-U.S. regulatory requirements will require that we expend time, money, and effort in production, recordkeeping, and compliance to assure that the product meets applicable specifications and other requirements. Any manufacturing facility must also pass a pre-approval inspection prior to regulatory approval. Failure to pass a pre-approval inspection might significantly delay regulatory approval of our product candidates. If we or any of our future collaborators fails to comply with these requirements with respect to the manufacture of any of our product candidates, regulatory action could limit the jurisdictions in which we are permitted to sell our products, if approved. As a result, our business, financial condition, and results of operations might be materially harmed.

We are exposed to the following risks with respect to the manufacture of our product candidates:

- If we are unable to establish our own manufacturing capabilities, we will need to identify manufacturers for commercial supply on acceptable terms, which we may not be able to do because the number of potential manufacturers is limited, and the FDA must evaluate any new or replacement contractor. This evaluation would generally require compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory approval, if any.

- We or any third-party manufacturers with whom we contract might be unable to formulate and manufacture our product candidates in the volume and of the quality required to meet our clinical and, if approved, commercial needs in a timely manner.

- Any third-party manufacturers with whom we contract might not perform as agreed or might not remain in the contract manufacturing business for the time required to supply our clinical studies or to produce, store and successfully distribute our products.

- One or more of any third-party manufacturers with whom we contract could be foreign, which increases the risk of shipping delays and adds the risk of import restrictions.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign requirements. Any internal manufacturing facilities we establish may fail to comply, and we would not have complete control over any third-party manufacturers' compliance, with these regulations and requirements.

- We may be required to obtain additional intellectual property rights from third parties in order to manufacture our product candidates, and if any third-party manufacturer makes improvements in the manufacturing process for our product candidates, we might not own, or might have to share, the intellectual property rights to the innovation with our licensors.

- We may be required to share our trade secrets and know-how with third parties, thereby risking the misappropriation or disclosure of our intellectual property by or to third parties.

- If we contract with third-party manufacturers, we might compete with other companies for access to these manufacturers' facilities and might be subject to manufacturing delays if the manufacturers give other clients higher priority than us.

Each of these risks could delay our development efforts, nonclinical studies and clinical studies or the approval, if any, of our product candidates by the FDA or applicable non-U.S. regulatory authorities or the commercialization of our product candidates and could result in higher costs or deprive us of potential product revenues. As a result, our business, financial condition, and results of operations might be materially harmed.

Any product candidates that we may discover and develop may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

In our industry, many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented their further development. Undesirable side effects caused by any product candidates that we may discover or develop, or safety, tolerability or toxicity issues that may occur in our nonclinical studies, clinical studies or in the future, could cause us or regulatory authorities to interrupt, restrict, delay, or halt clinical studies. Such results could also cause us to, or regulatory authorities to require us to, cease further development of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, prospects, financial condition and results of operations.

Additionally, if any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by these product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products and require us to take them off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a Risk Evaluation Mitigation Strategy (REMS) to ensure that the benefits of the product outweigh its risks;
- we may be required to change the way a product is administered, conduct additional clinical studies or change the labeling of a product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or any collaborators from achieving or maintaining market acceptance of our product candidates or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our product candidates.

Nonclinical studies may not be representative of disease behavior in clinical studies. The outcomes of nonclinical testing and clinical studies are uncertain, and results of nonclinical studies and earlier clinical studies may not be predictive of future clinical study results.

The results of nonclinical studies may not be representative of disease behavior in a clinical setting and thus may not be predictive of the outcomes of our clinical studies. In addition, the results of nonclinical studies and early clinical studies of product candidates may not be predictive of the results of later-stage clinical studies, and the results of any study or trial for any of our product candidates may not be as favorable as the results for any prior studies or trials, if at all.

Nonclinical studies and clinical testing are expensive, can take many years to complete and their outcomes are highly uncertain. Failure can occur at any time during the nonclinical study and clinical study processes due to inadequate performance of a drug candidate or inadequate adherence by patients or investigators to clinical study protocols. Further, clinical studies might not provide statistically significant data supporting a product candidate's safety and effectiveness to obtain the requisite regulatory approvals. In addition, there is a high failure rate for drugs and biologics proceeding through clinical studies. Our failure to replicate earlier positive results in later-stage clinical studies or otherwise demonstrate the required characteristics to support marketing approval for any of our product candidates would substantially harm our business, prospects, financial condition and results of operations.

If we are unable to hire and retain additional qualified personnel, our ability to grow our business might be harmed.

As of September 30, 2020, we had 140 employees and contracts with a number of temporary contractors, consultants and CROs. We will need to hire or contract with additional qualified personnel with expertise in clinical research and testing, formulation and manufacturing and sales and marketing to commercialize our HBV drug candidates and our microbiome biotherapeutic candidates or any other product candidate we may seek to develop. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success, and any failure to do so could have a material adverse impact on our business, financial condition and results of operations.

If we lose key management or scientific personnel, cannot recruit and retain qualified employees, officers, or other significant personnel or experience increases in our compensation costs, our business might materially suffer.

We are highly dependent on the services of our executive officers and senior management team. Our employment agreements with our executive officers and senior management team members do not ensure their retention. We do not currently maintain, nor do we intend to obtain in the future, "key man" life insurance that would compensate us in the event of the death or disability of any of the members of our management team. Our key management and scientific personnel are critical to our success, and loss of any of these key employees could have a material adverse impact on our business, financial condition and results of operations.

We are not currently profitable and might never become profitable.

We have a history of losses and expect to incur significant operating and capital expenditures and resultant substantial losses and negative operating cash flow for the next several years and beyond if we do not successfully launch and commercialize any product candidates from our HBV Cure or Microbiome programs. We might never achieve or maintain profitability. We anticipate that our expenses will continue to be substantial in the foreseeable future as we:

- advance VBR, H2158 and H3733, our first three HBV product candidates, through clinical development;
- advance M201, our first candidate from our Microbiome program, through Phase 1b clinical development;
- continue to undertake research and discovery efforts to identify potential additional product candidates in both our HBV Cure and Microbiome programs;

- seek regulatory approvals for our product candidates; and
- pursue our intellectual property strategy.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical studies or the development of any of our product candidates.

As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Our ability to generate revenue from the sale of products and achieve profitability will depend on, among other things:

- successful completion of research, nonclinical studies and clinical studies for our product candidates;
- obtaining necessary regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates;
- maintaining patent protection for our products, methods, processes and technologies and/or obtaining regulatory exclusivity;
- establishing manufacturing, distribution, sales, and marketing arrangements internally and/or with third parties for any approved products; and
- raising sufficient funds to finance our activities, if and when needed.

We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects, and results of operations might be materially adversely affected.

We are an early stage company and might not be able to commercialize any product candidates.

We are an early stage company and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any product candidates. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- continuing to undertake research and development and nonclinical studies and clinical studies;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales, marketing and distribution activities.

We currently do not have the infrastructure to manufacture, market and sell our product candidates. If we partner with one or more third-party entities, those commercial partners may demand and receive rights to control product development and commercialization. As a result, these commercial partners may conduct these programs and activities more slowly or in a different manner than expected. If any of these events were to occur, the development of any product candidate could be significantly delayed, more expensive or less lucrative to us than anticipated, any of which would have a significant adverse effect on our business.

Our failure to successfully commercialize our product candidates would negatively impact the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market our product candidates, if approved, or continue our operations.

There are substantial risks inherent in attempting to commercialize new drugs and biologics, and, as a result, we may not be able to successfully develop products for commercial use.

Scientific research and development require significant amounts of capital and takes a long time to reach commercial viability, if it can be achieved at all. To date, our research and development projects have not produced commercially approved drugs or biologics and may never do so. During the research and development process, we may experience technological barriers that we may be unable to overcome. Further, certain underlying premises in our development programs are not fully proven.

Our HBV therapy research and development efforts involve therapeutics based on modulating forms of HBV core proteins with core inhibitors. The development of our core inhibitor technology is in early stages, and the commercial feasibility and acceptance of our core inhibitor technology is unknown. More specifically, while there may be initial indications of decreasing cccDNA levels in some treated patients, the theory that treatment with core inhibitors may result in more rapid loss of cccDNA compared to conventional (standard of care) therapies is unproven. It is also unknown if the biomarkers assumed to be indicators of cccDNA pool levels (such as serum pgRNA, HBeAG, HBcrAg and, to a lesser extent, HBsAg in HBV patients) will be meaningfully altered in patients on treatment with core inhibitors. Additionally, even if core inhibitor technology is successful at targeting the HBV core protein and treatment is successful at reducing cccDNA levels in HBV patients, it may not result in a commercially approved drug if there is not a corresponding medical benefit related to the underlying HBV infection.

Similarly, our Microbiome program is based on a novel therapeutic approach designed to treat disorders associated with the microbiome. To our knowledge, no companies have received regulatory approval for, or manufactured on a commercial scale, any microbiome-based therapeutics. Our microbiome therapy candidates are in nonclinical and early clinical development, and our GEMICEL® dual-targeted release capsule formulation is novel and has not yet been shown to successfully deliver live bacteria in patients. The ability to deliver bacteria effectively and reliably to the GI tract is unproven, and, even if it can be proven, it may be difficult or impossible to provide the treatment economically. Because of these uncertainties, it is possible that no commercial products will be successfully developed. If we are unable to successfully develop commercial products, we will be unable to generate revenue from the sale of products or build a sustainable or profitable business.

A Fast Track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

If a drug or biologic is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug or biologic sponsor may apply for FDA Fast Track designation. Fast Track designation provides increased opportunities for sponsor meetings with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. In 2018 and July 2020, the FDA granted Fast Track designation to H0731 and H2158, respectively, for the treatment of patients with chronic HBV infection. We may seek Fast Track designation for other product candidates, but there is no assurance that it will be granted. Even with Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Fast Track designation does not assure ultimate approval by the FDA. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our product development program.

A breakthrough therapy designation by the FDA for any of our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for one or more of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for clinical development. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification and rescind the designation.

We will need additional financing to complete the development of any product candidate and fund our activities in the future.

We anticipate that we will incur operating losses for the next several years as we continue to develop our product candidates and our Microbiome platform as well as initiate development of any other product candidates and will require substantial funds during that time to support our operations. We expect that our current resources will provide us with sufficient capital to fund our operations for at least the next twelve months. However, we might consume our available capital before that time if, for example, we are not efficient in managing our resources or if we encounter unforeseen costs, delays or other issues or if regulatory requirements change or if clinical study timelines are accelerated. If that happens, we may need additional financing to continue the development of our HBV and microbiome product candidates, which we might seek and receive from the public financial markets, third-party commercial partners, private placements, debt financings or other sources. There is no assurance that we will be able to generate sufficient revenue from our collaborations or that we will be successful in raising any necessary additional capital on terms that are acceptable to us, or at all. For example, with the termination of the Allergan Agreement and return of the rights licensed thereunder, we are currently exploring strategic alternatives to continue development of our Microbiome programs. If other events such as this or other unforeseen circumstances occurred and we were unable to generate sufficient revenue or raise capital, we could be forced to delay, scale back or discontinue product development, sacrifice attractive business opportunities, cease operations entirely and sell or otherwise transfer all or substantially all of our remaining assets.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

In addition, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If another prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions or our ability to raise capital through the public financial markets, either of which could have a material adverse effect on our business.

We are dependent on an in-license relationship for each of our HBV Cure program and our Microbiome program.

Our license agreement with IURTC from whom we have licensed VBR and certain other HBV therapies, requires us to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to VBR and certain other HBV therapies and royalty payments and diligence fees. If we breach any of our obligations under our license agreement, we could lose our rights to VBR.

Our license with Therabiome, from whom we have licensed a delivery platform for our Microbiome program, also requires us to pay regulatory and clinical milestones as well as royalty payments to Therabiome. If we breach any of these obligations, we could lose our rights to the targeted delivery mechanism of our Microbiome program.

If we fail to comply with our obligations to our licensors, then they may have the right to terminate the license, in which event we would not be able to commercialize drug candidates or technologies that were covered by the license. In addition, the milestone and other payments associated with licenses will make it less profitable for us to develop our drug candidates than if we owned the technology ourselves.

Corporate and academic collaborators might take actions to delay, prevent, or undermine the success of our product candidates.

Our operating and financial strategy for the development, nonclinical and clinical testing, manufacture, and commercialization of drug candidates heavily depends on collaborating with corporations, academic institutions, licensors, licensees, and other parties. However, there can be no assurance that we will successfully establish or maintain these collaborations. For example, following its acquisition of Allergan, AbbVie terminated the Allergan Agreement effective October 10, 2020. We are currently exploring strategic alternatives to continue development of our Microbiome programs following the return of the rights licensed under the Allergan Agreement.

If a collaboration, such as the one with AbbVie, is terminated, replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and might not be within our power to influence. There can be no assurance that any collaborator will perform its obligations to our satisfaction or at all, that we will derive any revenue or profits from these collaborations, or that any collaborator will not compete with us. If any collaboration is not successful, we might require substantially greater capital to undertake development and marketing of our proposed products and might not be able to develop and market these products effectively, if at all. In addition, a lack of development and marketing collaborations might lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

We rely on data provided by our collaborators and others that has not been independently verified and could prove to be false, misleading, or incomplete.

We rely on third-party vendors, scientists, investigators and collaborators to provide us with significant data and other information related to our projects, nonclinical studies and clinical studies, and our business. If these third parties provide inaccurate, misleading, or incomplete data, our business, prospects, and results of operations could be materially adversely affected.

Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent this data from being compromised, and we rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result, a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyberterrorists, has generally increased as the number, intensity and

sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, any loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal, state and non-U.S. privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Clinical Health Act of 2009 (HITECH), and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission, state breach notification law and the European Union's General Data Protection Regulation (GDPR). We would also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Research, development and commercialization goals may not be achieved in the timeframes that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals, and make public statements regarding our expectations, regarding the timing of certain accomplishments, developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including, without limitation, the amount of time, effort and resources committed to our programs by us and any collaborators and the uncertainties inherent in the clinical development and regulatory approval process. As a result, there can be no assurance that we or any collaborators will initiate or complete clinical development activities, make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones as planned, our business could be materially adversely affected, and the price of our common stock could decline.

We lack suitable facilities for certain nonclinical and clinical testing and expect to rely on third parties to conduct some of our research and nonclinical testing and our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such research, testing or trials.

We do not have sufficient facilities to conduct all of our anticipated nonclinical and clinical testing. As a result, we expect to contract with third parties to conduct a significant portion of our nonclinical and clinical testing required for regulatory approval for our product candidates. We rely on the services of third parties to conduct studies on our behalf. If we are unable to retain or continue with third parties for these purposes on acceptable terms, we may be unable to successfully develop our product candidates. In addition, any failures by third parties to adequately perform their responsibilities may delay the submission of our product candidates for regulatory approval, which would impair our financial condition and business prospects.

Our reliance on these third parties for research and development activities also reduces our control over these activities but will not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, including, in the case of clinical studies, good clinical practices, and our reliance on third parties does not relieve us of our regulatory responsibilities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical and nonclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory

requirements or for other reasons, our research, nonclinical studies or clinical studies may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. As a result, our results of operations and business prospects would be harmed, our costs could increase and our ability to generate revenues from the sale of products could be delayed.

Developments by competitors might render our product candidates or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries are intensely competitive. In addition, the clinical and commercial landscape for HBV, UC, inflammatory bowel disease (IBD), including Crohn's disease, IBS, immune-mediated and metabolic disorders and oncology is rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We will compete with organizations that have existing treatments and that are or will be developing treatments for the indications that our product candidates target. If our competitors develop effective treatments for HBV, UC, IBD, IBS, immune-mediated and metabolic disorders and oncology or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects might be materially harmed, due to intense competition in these markets.

Companies with core inhibitor products or microbiome products may produce negative clinical data, which would adversely affect public perception of our product candidates, and may negatively impact regulatory approval of, or demand for, our potential products.

Negative data from clinical trials using core inhibitors or microbiome-based therapies (e.g., fecal transplant) could negatively impact the perception of the therapeutic use of our HBV or microbiome product candidates, respectively. This could negatively impact our ability to enroll patients in clinical trials. The clinical and commercial success of our potential products will depend in part on the public and clinical communities' acceptance of the use of core inhibitor product candidates and oral live microbial biotherapeutic products (LBPs). Moreover, our success depends upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of core inhibitor product candidates or LBPs we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which more clinical data may be available. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing core inhibitor therapies or microbiome therapies, even if not ultimately attributable to our product candidates, and any resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for our product candidates that are approved, if any, and a decrease in demand for any such products.

We might not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our current and future management and other administrative and operational resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We might seek to develop our business through acquisitions of or investment in new or complementary businesses, products or technologies, and the failure to manage these acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

We might consider opportunities to acquire or invest in other technologies, products and businesses that might enhance our capabilities or complement our current product candidates. Potential and completed acquisitions and strategic investments involve numerous risks, including potential problems or issues associated with the following:

- assimilating the acquired technologies, products or business operations;
- maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition or investment;
- diversion of our management's attention from our preexisting business;

- maintaining or obtaining the necessary regulatory approvals or complying with regulatory requirements; and
- adverse effects on existing business operations.

We have no current commitments with respect to any acquisition or investment in other technologies or businesses. We do not know if we will identify suitable acquisitions, whether we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired product, technology or business into our business or retain key personnel, suppliers or collaborators.

Our ability to successfully develop our business through acquisitions would depend on our ability to identify, negotiate, complete and integrate suitable target businesses or technologies and obtain any necessary financing. These efforts could be expensive and time consuming and might disrupt our ongoing operations. If we are unable to integrate efficiently any acquired business, technology or product into our business, our business and financial condition might be adversely affected.

Risks Related to Our Regulatory and Legal Environment

We are and will be subject to extensive and costly government regulation and the failure to comply with these regulations may have a material adverse effect on our operations and business.

Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice, state and local governments, and their respective foreign equivalents. Both before and after approval of any product, we and our collaborators, suppliers, contract manufacturers and clinical investigators are subject to extensive regulation by governmental authorities in the United States and other countries, covering, among other things, testing, manufacturing, quality control, clinical studies, post-marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. Failure to comply with applicable requirements could result in one or more of the following actions: warning or untitled letters; unanticipated expenditures; delays in approval or refusal to approve a product candidate; voluntary or mandatory product recall; product seizure; interruption of manufacturing or clinical studies; operating or marketing restrictions; injunctions; criminal prosecution and civil or criminal penalties including fines and other monetary penalties; exclusion from federal health care programs such as Medicare and Medicaid; adverse publicity; and disruptions to our business. Further, government investigations into potential violations of these laws would require us to expend considerable resources and face adverse publicity and the potential disruption of our business even if we are ultimately found not to have committed a violation. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained FDA approval for a given product and its uses. Such foreign regulation might be equally or more demanding than corresponding U.S. regulation.

Government regulation substantially increases the cost and risk of researching, developing, manufacturing, and selling our product candidates. The regulatory review and approval process, which includes nonclinical testing, manufacturing testing and clinical studies of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical studies and approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires submitting extensive nonclinical and clinical data and other supporting information for each proposed therapeutic indication in order to establish the product’s safety and efficacy for each intended use. The development and approval process might take many years, requires substantial resources, and might never lead to the approval of a product.

Even if we or our collaborators are able to obtain regulatory approval for a particular product, the approval might limit the intended medical uses for the product, limit our ability to promote, sell, and distribute the product, require that we conduct costly post-marketing surveillance, and/or require that we conduct ongoing post-marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, might require further regulatory review and approval. Once obtained, any approvals might be withdrawn, including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue.

If we, our collaborators, or our contract manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things, delays in the approval of applications or supplements to approved applications; refusal by a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; untitled letters or warning letters; fines; import and export restrictions; product recalls or seizures; injunctions; total or partial suspension of production; civil penalties; withdrawals of previously approved marketing applications; recommendations by the FDA or other regulatory authorities against governmental contracts; and/or criminal prosecutions.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we or our collaborators are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We, or any current or future collaborators, cannot assure you that we will receive the approvals necessary to commercialize for sale any of our product candidates, or any product candidate we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the applicable regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA, in the case of our HBV Cure program, or a BLA, in the case of our product candidates in our Microbiome program, demonstrating that the product candidate is safe for humans and effective for its intended use (for biological products, this standard is referred to as safe, pure and potent). This demonstration requires significant research, nonclinical studies, and clinical studies. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs or biological products that the FDA considers safe for humans and effective for their indicated uses. The FDA has substantial discretion in the approval process and might require us to conduct additional nonclinical and clinical testing, perform post-marketing studies or otherwise limit or impose conditions on any approval we obtain.

The approval process might also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals might:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we might otherwise enjoy.

Even if we comply with all FDA requests, the FDA might ultimately reject one or more of our NDAs or BLAs. We cannot be sure that we will ever obtain regulatory approval for our product candidates. Failure to obtain FDA approval of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate could be developed or obtained. There is no guarantee that we will ever be able to develop an existing, or acquire another, product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any product candidates. The risks associated with foreign regulatory approval processes are similar to the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

Even if our product candidates are approved, we and our collaborators will be subject to extensive post-approval regulation, including ongoing obligations and continued regulatory review, which may result in significant additional expense. If approved, our product candidates could be subject to post-marketing restrictions or withdrawal from the market and we, or any collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Once a product candidate is approved, numerous post-approval requirements apply. Among other things, we and our collaborators will be subject to requirements regarding testing, manufacturing, quality control, clinical studies, post-

marketing studies, labeling, advertising, promotion, distribution, import and export, governmental pricing, price reporting and rebate requirements. The holder of an approved NDA or BLA is subject to ongoing FDA oversight, monitoring and reporting obligations, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA or BLA. Application holders must submit new or supplemental applications and obtain FDA approval for changes to the approved product, product labeling, or manufacturing process, depending on the nature of the change. Application holders also must submit advertising and other promotional material to the FDA and report on ongoing clinical studies. The FDA also has the authority to require changes in the labeling of approved drug products and to require post-marketing studies. The FDA can also impose distribution and use restrictions under a REMS.

Advertising and promotional materials must comply with FDA rules in addition to other applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Manufacturing facilities remain subject to FDA inspection and must continue to adhere to the FDA's cGMP requirements. Sales, marketing, and scientific/educational grant programs, among other activities, must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Depending on the circumstances, failure to meet these post-approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, license revocation or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval or revise product labeling.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Even if we or our collaborators are able to commercialize any product candidates, those products may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, recently enacted legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the medicine in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

We have never commercialized a product, and even if any product candidate of ours is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians may be reluctant to take their patients off their current medications and switch their treatment regimen. Further, patients often acclimate to the treatment regime that they are currently taking and do not want to switch unless their physicians recommend

switching products or they are required to switch due to lack of coverage and adequate reimbursement. In addition, even if we are able to demonstrate our product candidates' safety and efficacy to the FDA and other regulators, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time and financial resources, and may not be successful. If any of our product candidates are approved but do not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- availability and adequacy of coverage and reimbursement from government payors, managed care plans and other third-party payors.

Our ability to commercialize any medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved medicines, and coverage may be more limited than the purposes for which the medicine is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any medicine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the medicine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the

United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to obtain promptly coverage and profitable payment rates from both government-funded and private payors for any approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

In the United States and in other countries, there have been, and we expect there will continue to be, a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform, as evidenced by the ACA.

Among the provisions of the ACA of importance to our potential drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologics;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices (which was increased to 70% as of January 1, 2019 under the Bipartisan Budget Act of 2018 (BBA));
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been many judicial, Presidential, and Congressional challenges to numerous aspects of the ACA, and the long ranging effects of these challenges on reimbursement by third-party payors, the viability of the ACA marketplace, providers, and potentially, our business are unknown at this time. In addition, the full impact of the ACA, any law repealing and/or replacing elements of it, and the political uncertainty surrounding any repeal or replacement legislation on our business remains unclear.

Further, in July 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of the U.S. Department of Health and Human Services (HHS) to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permitting the re-importation of insulin products and prioritizing finalization of FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical

manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center (FQHC) as part of the 340B drug program to purchase those drugs at the discounted price paid by the FQHC. It is unclear if, when, and to what extent the Executive Orders may be implemented. The regulatory and market implications of the Executive Orders are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs, if enacted and implemented, could decrease the price we receive for any products that we may develop and commercialize and could adversely affect our future revenues and prospects for profitability.

Further, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The continuing efforts of U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set satisfactory prices for our products, to generate revenues from the sale of products, and to achieve and maintain profitability.

We and our collaborators may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, and health information privacy and security laws, which could expose us or them to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our drug candidates and begin commercializing those drugs in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. There are ambiguities as to what is required to comply with these requirements, and if we fail to comply with any applicable federal, state or foreign legal requirement, we could be subject to penalties.

Regulators globally are imposing greater monetary fines for privacy violations. The GDPR, which went into effect on May 25, 2018, applies to any company established in the European Union (EU) as well as to those outside the EU if they collect and use personal data in connection with the offering goods or services to individuals in the EU or the monitoring of their behavior. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Noncompliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of developing our products and services or even prevent us from offering certain products in jurisdictions that we may operate in. Given the limited enforcement of the GDPR to date, particularly in the pharmaceutical space, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

California recently enacted the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

The Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act) requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to refine our disclosure controls and other procedures that are designed to ensure that the information that we are required to disclose in the reports that we will file with the SEC is properly recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are also continuing to improve our internal control over financial reporting. We have expended, and anticipate that we will continue to expend, significant resources in order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting.

Our current controls and any new controls that we develop in the future may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will be required to include in our periodic reports that will be filed with the SEC. If we were to have ineffective disclosure controls and procedures or internal control over financial reporting, our investors could lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

We face the risk of product liability claims and might not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that are inherent in the development of drugs and biotherapeutics. If the use of one or more of our product candidates or approved drugs, if any, harms people, we might be subject to costly and damaging product liability claims brought against us by clinical study participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability/clinical study insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop. We cannot predict all of the possible harms or side effects that might result and, therefore, the amount of insurance coverage we maintain might not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include product liability insurance covering the sale of commercial products if we obtain marketing approval for our drug candidates in development, but we might be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which might materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our products, our liability could exceed our total assets and our ability to pay the liability. Any successful product liability claims or series of claims brought against us would decrease our cash and could cause the value of our common stock to decrease.

We might be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research, development and manufacturing activities and/or those of our third-party contractors might involve the controlled use of hazardous materials and chemicals. Although we will strive to have our safety procedures, and those of our contractors, for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages, and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products might require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations. We currently do not carry hazardous materials liability insurance. We intend to obtain such insurance in the future, if necessary, but cannot give assurance that we could obtain such coverage.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and harm our reputation.

We are exposed to the risk of fraud or other misconduct, including intentional failure to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the United States Foreign Corrupt Practices Act (the FCPA), the U.K. Bribery Act 2010, the PRC Criminal Law, the PRC Anti-unfair Competition Law and other anti-bribery laws;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

Misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical studies, creating fraudulent data in our nonclinical studies or clinical studies or illegal misappropriation of product materials, which could result in regulatory sanctions, delays in clinical studies, or serious harm to our reputation. We have adopted a code of conduct for our directors, officers and employees (the Code of Conduct), but

it is not always possible to identify and deter employee misconduct. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could harm our business, results of operations, financial condition and cash flows, including through the imposition of significant fines or other sanctions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, Trade Laws). We can face serious consequences for violations.

Among other matters, Trade Laws prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities, particularly in China, to increase in time. We engage third parties for clinical studies and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

We have international operations, including in China, and conduct clinical studies outside of the United States. A number of risks associated with international operations could materially and adversely affect our business.

We expect to be subject to a number of risks related with our international operations, many of which may be beyond our control. These risks include:

- different regulatory requirements for drug approvals in foreign countries;
- different standards of care in various countries that could complicate the evaluation of our product candidates;
- different U.S. and foreign drug import and export rules;
- different reimbursement systems and different competitive drugs indicated to treat the indication for which our product candidates are being developed;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- compliance with the FCPA and other anti-corruption and anti-bribery laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations and compliance with foreign currency exchange rules, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- business interruptions resulting from geopolitical actions, including tariffs, war and terrorism, natural disasters or outbreaks of disease, such as the spread of the novel strain of coronavirus and the resulting COVID-19 pandemic impacting all countries, including China.

Risks Related to Our Intellectual Property

Our business depends on protecting our intellectual property.

If we and our licensors, IURTC and Therabiome, do not obtain protection for our respective intellectual property rights, our competitors might be able to take advantage of our research and development efforts to develop competing drugs. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and chemical and biological compositions that are important to our business. To date, we and our licensors have filed patent applications intended to cover our products candidates and their methods of use. Although we co-own and have in-licensed two issued patents in the U.S. directed to compositions of matter that includes H0731, which are expected to expire in 2035 and 2036, and we have in-licensed issued U.S. patents related to delivery technology for our Microbiome program, which are expected to expire in 2034, we do not own or have any rights to any issued patents that cover any of our other product candidates, and we cannot be certain that we will secure any rights to any issued patents with claims that cover any of our proprietary product candidates and technologies. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent process also is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- Any patent rights, if obtained, might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the United States or in international markets;
- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful; and
- Countries other than the United States might have patent laws that provide less protection than those governing U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the U.S. Patent and Trademark Office (the USPTO) and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections, if obtained, will prove inadequate. Our business and prospects will be harmed if we fail to obtain these protections or they prove insufficient.

If we fail to comply with our obligations under our license agreements, we could lose rights to our product candidates or key technologies.

We have obtained rights to develop, market and sell some of our product candidates and technologies through intellectual property license agreements with third parties, including IURTC and Therabiome. These license agreements impose various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under our license agreements, we could lose some or all of our rights to develop, market and

sell products covered by these licenses, and our ability to form collaborations or partnerships may be impaired. In addition, disputes may arise under our license agreements with third parties, which could prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and to develop and commercialize the affected product candidates.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. There is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we were not successful in defending our intellectual property, our competitors could develop and market products based on our discoveries, which may reduce demand for our products.

We rely on trade secret protections through confidentiality agreements with our employees, collaborators and other parties, and the breach of these agreements could adversely affect our business and prospects.

We rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality, invention, and nondisclosure agreements with our employees, scientific advisors, consultants, collaborators, suppliers, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

If our employees or consultants breach their confidentiality obligations, to be able to enforce these confidentiality provisions, we would need to know of the breach and have sufficient funds to enforce the provisions. We cannot assure you that we would know of or be able to afford enforcement of any breach. In addition, such provisions are subject to state law and interpretation by courts, which could limit the scope and duration of these provisions. Any limitation on or non-enforcement of these confidentiality provisions could have an adverse effect on our business.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Our competitors may have filed, and may in the future file, patent applications covering products and technologies similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights from third parties to issued patents covering such products and technologies. We cannot guarantee that the manufacture, use or marketing of any product candidates that we develop will not infringe third-party patents.

A third party may claim that we are using inventions covered by the third party’s patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. Patent litigation is costly and time consuming. We may not have sufficient resources to address these actions, and such actions could affect our results of operations and divert the attention of managerial and scientific personnel.

If a patent infringement suit were brought against us, we may be forced to stop or delay developing, manufacturing, or selling potential products that are claimed to infringe a third party’s intellectual property, unless that third party grants us rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue development, manufacture or sale of our products. If we are unable to obtain a license or develop or obtain non-infringing technology, or if we fail to defend an infringement action successfully, or if we are found to have infringed a valid patent, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates, any of which could harm our business significantly.

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market.

Any disclosure to or misappropriation by third parties of our patents, trade secrets or confidential information could compromise our competitive position. We rely upon a combination of patents, trade secret protection and contractual arrangements to protect the intellectual property related to our technologies. We will only be able to protect our products and proprietary information and technology by preventing unauthorized use by third parties to the extent that our patents, trade secrets, and contractual position allow us to do so. The legal systems of certain countries, particularly countries such as China, do not always favor the enforcement of patents, trade secrets, and other intellectual property rights, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop infringement of our patents, misappropriation of our trade secrets, or marketing of competing products in violation of our proprietary rights.

We may in the future be involved in legal or administrative proceedings involving our intellectual property initiated by third parties, and which proceedings can result in significant costs and commitment of management time and attention and could put our patents in these territories at risk of being invalidated or interpreted narrowly, or our patent applications at risk of not being granted and could provoke third parties to assert claims against us.

We may in the future be involved in initiating legal or administrative proceedings involving the product candidates and intellectual property of our competitors. These proceedings can result in significant costs and commitment of management time and attention, and there can be no assurance that our efforts would be successful in preventing or limiting the ability of our competitors to market competing products.

Composition-of-matter patents relating to the active pharmaceutical ingredient (API) are generally considered to be the strongest form of intellectual property protection for pharmaceutical products. Such patents provide protection not limited to any one method of use. Method-of-use patents protect the use of a product for the specified method(s), and do not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. We rely on a combination of these and other types of patents to protect our product candidates, and there can be no assurance that our intellectual property will create and sustain the competitive position of our product candidates.

Biotechnology and pharmaceutical product patents involve highly complex legal and scientific questions. Any patent applications that we own or license may fail to result in issued patents. Even if patents do successfully issue from our applications, third parties may challenge their validity or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Even if our patents and patent applications are not challenged by third parties, those patents and patent applications may not prevent others from designing around our claims and may not otherwise adequately protect our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, competitors with significantly greater resources could threaten our ability to commercialize our product candidates. Discoveries are generally published in the scientific literature well after their actual development, and patent applications in the United States and other countries are typically not published until 18 months after filing, and in some cases are never published. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or patent applications, or that we or our licensors were the first to file for patent protection covering such inventions. Subject to meeting other requirements for patentability, for U.S. patent applications filed prior to March 16, 2013, the first to invent the claimed invention is entitled to receive patent protection for that invention while, outside the United States, the first to file a patent application encompassing the invention is entitled to patent protection for the invention. The United States moved to a “first to file” system under the Leahy-Smith America Invents Act (AIA), effective March 16, 2013. This system includes procedures for challenging issued patents and pending patent applications, which may create additional uncertainty. We may become involved in any variety of proceedings challenging our patents and patent applications or the patents and patent applications of others, and the outcome of any such proceedings are highly uncertain. An unfavorable outcome in any such proceedings could reduce the scope of, invalidate, and/or find our patent rights unenforceable, allowing third parties to commercialize our technology and compete directly with us, or result in our inability to manufacture, develop or commercialize our product candidates without infringing the patent rights of others. In addition to ongoing changes with the AIA and USPTO regulations, recent decisions of the Supreme Court of the United States, and the possibility of statutory change to patent subject matter eligibility law advocated by such groups as the Intellectual Property Owners Association and the American Intellectual Property Law Association, provide additional uncertainty.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors and any third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. Furthermore, the laws of some foreign countries, in particular China, where we anticipate increasing our activity and commercializing our product candidates, do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business and operations.

Our reliance on third parties and agreements with collaboration partners requires us to share our trade secrets, which increases the possibility that a competitor may discover them or that our trade secrets will be misappropriated or disclosed.

Our reliance on third-party contractors to develop and manufacture our product candidates is based upon agreements that limit the rights of the third parties to use or disclose our confidential information, including our trade secrets and know-how. Despite the contractual provisions, the need to share trade secrets and other confidential information increases the risk that such trade secrets and information are disclosed or used, even if unintentionally, in violation of these agreements. In the highly competitive markets in which our product candidates are expected to compete, protecting our trade secrets, including our strategies for addressing competing products, is imperative, and any unauthorized use or disclosure could impair our competitive position and may have a material adverse effect on our business and operations.

In addition, some of our collaboration partners are larger, more complex organizations than ours, and the risk of inadvertent disclosure of our proprietary information may be increased despite their internal procedures and contractual obligations in place with our collaboration partners. Despite our efforts to protect our trade secrets and other confidential information, a competitor’s discovery of such trade secrets and information could impair our competitive position and have an adverse impact on our business.

We are developing an extensive worldwide patent portfolio. The cost of maintaining our patent protection is high and maintaining our patent protection requires continuous review and compliance in order to maintain worldwide patent protection. We may not be able to effectively maintain our intellectual property position throughout the major markets of the world.

The USPTO and foreign patent authorities require maintenance fees and payments as well as continued compliance with a number of procedural and documentary requirements. Noncompliance may result in abandonment or lapse of the subject patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance may result in reduced royalty payments for lack of patent coverage in a particular jurisdiction from our collaboration partners or may result in competition, either of which could have a material adverse effect on our business.

We have made, and will continue to make, certain strategic decisions in balancing costs and the potential protection afforded by the patent laws of certain countries. As a result, we may not be able to prevent third parties from practicing our inventions in all countries throughout the world, or from selling or importing products made using our inventions in and into the United States or other countries. Third parties may use our technologies in territories in which we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories which provide inadequate enforcement mechanisms, even if we have patent protection. Such third-party products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Intellectual property rights do not address all potential threats to any competitive advantage we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make compounds that are the same as or similar to our current or future product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed.
- We or any of our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions.
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- The prosecution of our pending patent applications may not result in granted patents.
- Granted patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product.
- Our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates.

The existence of counterfeit pharmaceutical products in pharmaceutical markets may damage our brand and reputation and have a material adverse effect on our business, operations and prospects.

Counterfeit products, including counterfeit pharmaceutical products, are a significant problem, particularly in China. Counterfeit pharmaceuticals are products sold or used for research under the same or similar names, or similar mechanism of action or product class, but which are sold without proper licenses or approvals. The proliferation of counterfeit pharmaceuticals has grown in recent years and may continue to grow in the future. Such products may be used for indications or purposes that are not recommended or approved or for which there is no data or inadequate data with regard to safety or efficacy. Such products divert sales from genuine products, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. If counterfeit pharmaceuticals illegally sold or used for research result in adverse events or side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Consumers may buy counterfeit pharmaceuticals that are in direct competition with our pharmaceuticals, which could have an adverse impact on our revenues, business and results of operations. In addition, counterfeit products could be used in nonclinical studies or clinical studies or could otherwise produce undesirable side effects or adverse events that may be attributed to our products as well, which could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. In China, although the government has recently been increasingly active in policing counterfeit pharmaceuticals, there is not yet an effective counterfeit pharmaceutical regulation control and enforcement system. As a result, we may not be able to prevent third parties from selling or purporting to sell our products in China. The existence of and any increase in the sales and production of counterfeit pharmaceuticals, or the technological capabilities of counterfeiters, could negatively impact our revenues, brand reputation, business and results of operations.

Risks Related to Our Common Stock

The price of our common stock might fluctuate significantly, and you could lose all or part of your investment.

The price of our common stock fluctuates widely. Continued volatility in the market price of our common stock might prevent a stockholder from being able to sell shares of our common stock at or above the price paid for such shares. The trading price of our common stock might be volatile and subject to wide price fluctuations in response to various factors, including:

- the progress, results and timing of our clinical studies and nonclinical studies and other studies involving our product candidates;
- success or failure of our product candidates;
- the receipt or loss of required regulatory approvals for our product candidates;
- availability of capital;
- future issuances by us of our common stock or securities exercisable for or convertible into common stock;
- sale of shares of our common stock by our significant stockholders or members of our management;
- additions or departures of key personnel;
- investor perceptions of us and the pharmaceutical industry;
- issuance of new or changed securities analysts' reports or recommendations, or the announcement of any changes to our credit rating;
- introduction of new products or announcements of significant contracts, acquisitions or capital commitments by us or our competitors;
- threatened or actual litigation and government investigations;
- legislative, political or regulatory developments;
- the overall performance of the equity markets;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- general economic conditions;
- changes in interest rates; and
- changes in accounting standards, policies, guidance, interpretations or principles.

These and other factors might cause the market price of our common stock to fluctuate substantially, which might limit or prevent investors from readily selling their shares of our common stock and might otherwise negatively affect the liquidity of our common stock. In addition, this year, the stock market has experienced significant price and volume fluctuations related to the COVID-19 pandemic. This volatility has had a significant impact on the market price of our common stock and securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors unrelated to our business and operations, and these fluctuations could materially reduce our share price.

We might not be able to maintain the listing of our common stock on the Nasdaq Global Select Market.

Our common stock is listed on the Nasdaq Global Select Market under the symbol "ASMB." We might not be able to maintain the listing standards of that exchange. If we fail to maintain the listing requirements, our common stock might trade on the OTC Bulletin Board or in the "pink sheets" maintained by OTC Markets Group Inc. These alternative markets are generally considered to be markets that are less efficient and less broad than the Nasdaq Global Select Market. A delisting of our common stock from the Nasdaq Global Select Market and our inability to list the stock on another national securities exchange could negatively impact us by: (1) reducing the liquidity and market price of our common stock; (2) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (3) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets and (4) impairing our ability to provide equity incentives to our employees.

We may be subject to securities litigation, which is expensive and could divert management's attention.

The market price of our common stock may be volatile, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our ability to use our net operating loss and credit carryforwards to offset future taxable income may be subject to certain limitations.

At December 31, 2019, we had potentially utilizable gross Federal net operating loss carryforwards of $297.6 million with $182.9 million of net operating losses that carry forward indefinitely and $114.7 million of net operating losses which begin to expire in 2027. There are State net operating loss carryforwards of $309.3 million with $1.0 million carrying forward indefinitely and $308.3 million beginning to expire in 2031. In addition, we have Federal research and development credit carryforwards of $9.0 million which begin to expire in 2028 if not utilized and California research and development credit carryforwards of $5.3 million, which will carryforward indefinitely. Our ability to utilize our net operating loss and credit carryforwards is dependent upon our ability to generate taxable income in future periods and may be limited due to restrictions imposed on utilization of net operating loss and credit carryforwards under federal and state laws upon a change in ownership.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, a corporation that undergoes an "ownership change," is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards (NOLs) and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three-year period (calculated on a rolling basis). We have determined that an ownership change occurred in each of December 2010, January 2013 and October 2014. The result of these ownership changes is that $39.8 million of our $337.4 million of Federal net operating losses will not be available to us to offset future taxable income leaving potentially utilizable gross Federal net operating loss carryforwards of $297.6 million. In addition, we may experience ownership changes in the future, some of which are outside our control. Accordingly, we may not be able to utilize a material portion of our net operating losses or credits. Limitations on our ability to utilize our net operating losses to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Because U.S. federal net operating losses incurred in taxable periods beginning before January 1, 2018 generally may be carried forward for up to 20 years, the annual limitation may effectively provide a cap on the cumulative amount of pre-ownership change losses, including certain recognized built-in losses that may be utilized. Such pre-ownership change losses in excess of the cap may be lost. In addition, if an ownership change were to occur, it is possible that the limitations imposed on our ability to use pre-ownership change losses and certain recognized built-in losses could cause a net increase in our U.S. federal income tax liability and require U.S. federal income taxes to be paid earlier than otherwise would be paid if such limitations were not in effect. Further, if for financial reporting purposes the amount or value of these deferred tax assets is reduced, such reduction would have a negative impact on the book value of our common stock.

In addition, under the Tax Cust and Jobs Act (the Tax Act), the amount of U.S. federal net operating losses generated in taxable periods beginning after December 31, 2017 that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The Tax Act generally eliminates the ability to carry back any post-2017 NOL to prior taxable years, while allowing unused post-2017 NOLs to be carried forward indefinitely. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law by President Trump in March 2020. The CARES Act allows NOLs in tax periods beginning after December 31, 2017 and beginning before January 1, 2021 to be carried back five years, carried forward indefinitely, and permitted to deduct 100% of our taxable income for tax periods beginning before January 1, 2021. In tax periods beginning after December 31, 2020, the 80% taxable income limit discussed above will apply to all U.S. NOLs generated in taxable periods beginning after December 31, 2017.

There is a risk that due to ownership changes, changes in law or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

We do not intend to pay dividends for the foreseeable future and our stock may not appreciate in value.

We currently intend to retain our future earnings, if any, to finance the operation and growth of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in shares of our common stock will depend upon any future appreciation in its value. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained.

The requirements of being a public company add to our operating costs and might strain our resources and distract our management.

As a public company, we face increased legal, accounting, administrative and other costs and expenses not faced by private companies. We have incurred and will continue to incur significant additional legal, accounting and other expenses to which we were not subject to as a private company, including expenses related to our efforts in complying with the requirements of the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and other public company disclosure and corporate governance requirements and responding to requests of government regulators. We are subject to the reporting requirements of the Exchange Act, which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act, and the listing standards of the Nasdaq Global Select Market, each of which imposes additional reporting and other obligations on public companies. Although we are currently unable to estimate these costs with any degree of certainty, we expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly and place significant strain on our personnel, systems and resources. These increased costs will require us to divert a significant amount of money that we could otherwise use to develop our product candidates or otherwise expand our business. Complying with these requirements might divert management's attention from other business concerns, which could have a material adverse effect on our prospects, business, and financial condition. If we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Several provisions of the Delaware General Corporation Law and our charter documents could discourage, delay or prevent a merger or acquisition, which could adversely affect the market price of our securities.

Several provisions of the Delaware General Corporation Law and our charter documents could discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, and the market price of our securities could be reduced as a result. These provisions may include:

- authorizing the issuance of "blank check" preferred stock, the terms of which we may establish and shares of which we may issue without stockholders' approval;
- prohibiting us from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless certain provisions are met;
- prohibiting cumulative voting in the election of directors;

- prohibiting shareholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

If securities analysts downgrade our stock or cease coverage of us, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. Currently, a limited number of financial analysts publish reports about us and our business. We do not control these analysts or any other analysts. Furthermore, there are many large, well-established, publicly traded companies active in our industry and market, which may mean that it is less likely that we will receive widespread analyst coverage. If any analyst who covers us downgrades our stock, our stock price could decline rapidly. If one or more analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

(a) *Exhibits.* The following exhibits are filed as part of this quarterly report on Form 10-Q:

Exhibit Number	Description of Document	Filed Herewith	Incorporated by Reference from	Date	Number
10.1†	Amendment No. 1 to Exclusive License Agreement, by and between Assembly Biosciences, Inc. and the Indiana University Research and Technology Corporation.	X			
10.2†	Amendment No. 2 to Exclusive License Agreement by and between Assembly Biosciences, Inc. and the Indiana University Research and Technology Corporation.	X			
10.3†‡	Collaboration Agreement, dated as of July 17, 2020, by and between Assembly Biosciences, Inc. and BeiGene, Ltd.	X			
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2*	Certification of the Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)	X			

† The schedules to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

‡ Portions of this exhibit that are both not material and would likely cause competitive harm to the registrant if publicly disclosed have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

* The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of Assembly Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Assembly Biosciences, Inc.

Date: November 5, 2020

By: /s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President
(Principal Executive Officer)

Date: November 5, 2020

By: /s/ Thomas J. Russo, CFA
Thomas J. Russo, CFA
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

[* * *] Portions of this exhibit that are both not material and would likely cause competitive harm to the registrant if publicly disclosed have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

AMENDMENT #1 TO EXCLUSIVE LICENSE AGREEMENT

This Amendment #1 to Exclusive License Agreement ("Amendment #1") is entered into as of February 28, 2017 (the "Amendment #1 Effective Date") by and between The Indiana University Research and Technology Corporation, a non-profit corporation organized under the laws of the state of Indiana, having its principal offices at 518 Indiana Ave, Indianapolis, IN 46202 ("IURTC") and Assembly Biosciences, Inc. (the parent company and assignee of Assembly Pharmaceuticals, Inc.), a company organized under the laws of the state of Delaware, having its principal offices at 11711 N. Meridian Street, Suite 310, Carmel, Indiana, 46032 ("Assembly") and acknowledged by Assembly Pharmaceuticals, Inc., a Delaware corporation and wholly owned subsidiary of Assembly ("AP"). IURTC and Assembly may each be referred to herein as a "Party" and collectively as the "Parties".

WHEREAS, IURTC and Assembly, as assignee of AP, are parties to that ce1tain Exclusive License Agreement dated as of September 3, 2013 (the "License Agreement").

WHEREAS, the Parties desire to amend the License Agreement to include within the scope of the exclusive license certain additional patent applications, including patent applications that are co- owned by Assembly.

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein and in the License Agreement, IURTC and Assembly agree as follows:

1. Section 3.5 of the License Agreement is hereby deleted and replaced in its entirety with the following:

"3.5 This Agreement provides Assembly and Sublicensees no ownership rights of any kind in the Patent Rights, provided that the Parties acknowledge that Assembly has joint ownership rights in certain Patent Rights as set forth on Exhibit A. All ownership rights, other than such joint ownership rights owned by Assembly, remain the property of the Institutions and/or IURTC."

2. The following is hereby added as Section 9.8 of the License Agreement:

"9.8 Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that for the patent applications listed on Exhibit A that are identified as "Protein Modulator Patents" (including all associated Patent Rights) (such patent applications and associated Patent Rights, collectively, the "Protein Modulator Patent Rights") that Assembly is a co-owner of the Protein Modulator Patent Rights and, notwithstanding anything in Sections 9.1 through 9.7 to the contrary , the Parties agree that:

9.8.1 Assembly will have exclusive control of the preparation, filing, prosecution, issue and maintenance of the Protein Modulator Patent Rights. Assembly will select qualified patent counsel reasonably acceptable to IURTC to prepare, file, prosecute and maintain the Protein Modulator Patent Rights. Assembly will keep IURTC fully informed of patent prosecution, will seek IURTC's comments and suggestions prior to taking material actions for the same, and will take all prosecution actions reasonably recommended by IURTC which would expand the scope of rights sought.

9.8.2 Assembly will authorize IURTC to communicate directly with Assembly's patent counsel. All information exchanged among Assembly's counsel, the Parties, and/or the inventors regarding the preparation, filing, prosecution, issue, or maintenance of the Protein Modulator Patent Rights will be deemed Confidential Information. In addition, the Parties acknowledge and agree that with regard to such preparation, filing, prosecution, issue, and maintenance of the Protein Modulator Patent Rights, the interests of the Parties as licensee and licensor are to obtain the strongest and broadest patent protection possible, and as such are aligned and legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Protein Modulator Patent Rights, including without limitation, privilege under the common interest doctrine and similar or related doctrines.

9.8.3 Assembly will not abandon the prosecution of any patent application or the maintenance of any patent under the Protein Modulator Patent Rights without prior written notice to IURTC. Upon receiving such written notice, IURTC, at its sole option, may take over the prosecution of any such patent application or the maintenance of any such issued patent in accordance with Sections 9.1 through 9.7."

3. Exhibit A of the License Agreement is hereby deleted in its entirety and is replaced with the Exhibit A attached hereto.

4. Except as specifically modified by this Amendment #1, the Parties agree that all of the terms and conditions set forth in the License Agreement remain in full force and effect.

5. The Parties and AP acknowledge and agree that AP has assigned the License Agreement to Assembly and Assembly has assumed all the obligations and liabilities of AP under the License Agreement following that certain merger by and among Assembly, AP and a wholly owned subsidiary of Assembly effected on July 11, 2014.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Amendment #1 to be executed by their duly authorized representatives as of the Amendment #1 Effective Date.

ASSEMBLY BIOSCIENCES, INC.

By: /s/ Derek A. Small
Name: Derek A Small
Title: CEO

THE INDIANA UNIVERSITY RESEARCH AND TECHNOLOGY CORPORATION

By: /s/ Marie Kerbeshian
Name: Marie Kerbeshian
Title: Vice President Office of Technology Commercialization

Solely for Purposes of Acknowledging the assignment of the License Agreement:

ASSEMBLY PHARMACEUTICALS, INC.

By: /s/ Derek A. Small
Name: Derek A Small
Title: CEO

Exhibit A
Patent Rights

[* * *]

[Signature Page to Amendment No. 1 to Exclusive License Agreement]

Exhibit 10.2

[* * *] Portions of this exhibit that are both not material and would likely cause competitive harm to the registrant if publicly disclosed have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

IURTC Agreement No. 2020-0121

AMENDMENT #2 TO EXCLUSIVE LICENSE AGREEMENT

This Amendment #2 to Exclusive License Agreement (this "Amendment #2") is entered into and effective as of July 10, 2020 (the "Amendment #2 Effective Date") by and between Indiana University Research and Technology Corporation, a non-profit corporation organized under the laws of the state of Indiana, having its principal offices at 518 Indiana Ave., Indianapolis, Indiana 46202 ("IURTC") and Assembly Biosciences, Inc. (the parent company and assignee of Assembly Pharmaceuticals, Inc.), a Delaware corporation, having its principal offices at 331 Oyster Point Blvd., Fourth Floor, South San Francisco, California 94080 ("Assembly"). IURTC and Assembly may each be referred to herein as a "Party" and collectively as the "Parties".

WHEREAS, IURTC and Assembly, as assignee of Assembly Pharmaceuticals, Inc., a Delaware corporation and wholly owned subsidiary of Assembly, are parties to that certain Exclusive License Agreement dated as of September 3, 2013 with IURTC Agreement No. 2014-0134 (formerly ASS-0313-BB) as amended by Amendment #1 to Exclsuive License Agreement dated as of February 28, 2017 with IURTC Agreement No. 2017-0180 (collectively, the "License Agreement").

WHEREAS, the Parties desire to amend the License Agreement to clarify the rights of Sublicensees under the License Agreement and clarify the scope of the Patent Rights subject to the License Agreement; and

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein and in the License Agreement, IURTC and Assembly agree as follows:

1. Amendments to the License Agreement. As of the Amendment #2 Effective Date, the License Agreement is hereby amended or modified as follows:

1.1 The first paragraph of Section 3.3 of the License Agreement is hereby deleted and replaced in its entirety as follows:

"Assembly may grant Sublicenses to non-Affiliate third parties under this Agreement. Only Assembly, and not its Affiliates, is permitted to grant Sublicenses. Notwithstanding the foregoing, Sublicensees may grant sub-sublicenses (through multiple tiers) under the Agreement solely: (i) to their Affiliates, *provided* that any such sub-sublicenses shall automatically terminate if the sub-sublicensee party thereto ceases to be an Affiliate of the Sublicensee; (ii) subject to the terms of the Sublicense, to contract research organizations, distributors and other third party subcontractors for the sole purpose of performing Sublicensee's obligations under the Sublicense; and (iii) to any other third party subject to IURTC's prior written consent, not to be unreasonably withheld, conditioned or delayed."

1.2 Section 3.3.4 of the License Agreement is hereby deleted and replaced in its entirety as follows:

"Assembly agrees to be fully responsible for the performance of its Sublicensees hereunder and any sub-sublicensees under any sub-sublicenses granted by Sublicensee. Any act or omission by a Sublicensee or sub-sublicensee that would be a breach of this Agreement if imputed to Assembly will be deemed to be a breach by Assembly of this Agreement."

1.3 Section 6.1.1 of the License Agreement is deleted and replaced in its entirety as follows:

"Checks will be sent to:
Indiana University Research and Technology Corporation
Attn: Innovation and Commercialization Office
518 Indiana Avenue
Indianapolis, IN 46202

The IURTC Agreement No. 2014-0134 (formerly ASP- 0313 BB) and purpose of the payment will be included with the check."

1.4 Section 15 of the License Agreement is hereby modified to replace IURTC's notice address as follows:

"**Notice**: Any required or permissive notice under this Agreement will be sufficient if in writing and delivered personally, by recognized national overnight courier, or by registered or certified mail, postage prepaid and return receipt requested, to the address below and will be deemed to have been given as of the date shown on the receipt if by certified or registered mail, or the day following dispatch if by overnight courier.

If to IURTC:
The Trustees of Indiana University
Attn: Innovation and Commercialization Office
IURTC Agreement No. 2014-0134 (formerly ASP-0313-BB)
107 S. Indiana Ave., Bryan Hall 211
Bloomington, IN 47405

With copy to:
Indiana University Research and Technology Corporation
Attn: Innovation and Commercialization Office
IURTC Agreement No. 2014-0134 (formerly ASP-0313-BB)
518 Indiana Avenue
Indianapolis, IN 46202

If to Assembly:
Assembly Biosciences, Inc.
Attn: Chief Legal and Business Officer
331 Oyster Point Blvd., Fourth Floor
South San Francisco, CA 94080"

1.5 Exhibit A of the License Agreement is hereby deleted and replaced in its entirety with the Exhibit A attached hereto.

2. Limited Effect. Except as specifically modified by this Amendment #2, the Parties agree that all of the terms and conditions set forth in the License Agreement remain in full force and effect.

3. Counterparts; Signatures. This Amendment #2 may be executed in any number of counterparts, each of which taken together shall be deemed to constitute one and the same agreement. The Parties agree that execution of this Amendment #2 by industry standard electronic signature software and/or by exchanging executed signature pages in .pdf format via e-mail shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or related to this Amendment #2, each party hereby waives any right to raise any defense or waiver based upon execution of this Amendment #2 by means of such electronic signatures or maintenance of the executed agreement electronically.

IN WITNESS WHEREOF, the parties have caused this Amendment #2 to be executed and delivered by their duly authorized representatives as of the Amendment #2 Effective Date.

ASSEMBLY BIOSCIENCES, INC.

By: /s/ Jason A. Okazaki
Name: Jason A. Okazaki
Title: Chief Legal and Business Officer

INDIANA UNIVERSITY RESEARCH AND TECHNOLOGY CORPORATION

By: /s/ Simran Trana
Name: Simran Trana
Title: Associate VP, ICO

Exhibit A
Patent Rights

[* * *]

[* * *] Portions of this exhibit that are both not material and would likely cause competitive harm to the registrant if publicly disclosed have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

COLLABORATION AGREEMENT

This **Collaboration Agreement** (this "**Agreement**") is made as of July 17, 2020 (the "**Effective Date**"), by and between **Assembly Biosciences, Inc.**, a corporation organized and existing under the laws of Delaware ("**AssemblyBio**"), having a place of business at 331 Oyster Point Blvd., 4th Floor, South San Francisco, CA 94080, and **BeiGene, Ltd.**, a Cayman Island exempted company incorporated with limited liability ("**BeiGene**"), having a place of business at c/o Mourant Governance Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, PO Box 1348, Grand Cayman KY1-1108, Cayman Islands. AssemblyBio and BeiGene are referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**."

BACKGROUND

A. AssemblyBio is a biopharmaceutical company that is developing proprietary compounds known as ABI-H0731, ABI-H2158, and ABI-H3733 for the treatment of hepatitis B (HBV) and controls certain patents and know-how relating to such compounds;

B. BeiGene is a biopharmaceutical company engaged in the research, development and commercialization of pharmaceutical products;

C. BeiGene wishes to obtain from AssemblyBio an exclusive license to develop and commercialize ABI-H0731, ABI-H2158, and ABI-H3733 in the Field in the Territory, and AssemblyBio is willing to grant such a license to BeiGene, all in accordance with the terms and conditions set forth herein; and

D. The Parties originally entered into the Agreement as of the Effective Date. The Parties are re-executing this version of the Agreement as of November 2, 2020 to correct certain section and exhibit references. The Parties acknowledge and agree this version supersedes and replaces in its entirety, effective as of the Effective Date, the version of this Agreement previously executed by the Parties as of the Effective Date.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein below, and other good and valuable consideration, the sufficiency of which is hereby acknowledged by both Parties, the Parties agree as follows:

ARTICLE 1
DEFINITIONS & INTERPRETATION

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, whether used in the singular or plural, shall have the meanings specified.

1.1 "**Accounting Standard**" means (a) with respect to AssemblyBio, GAAP, and (b) with respect to BeiGene, GAAP (or IFRS, if applicable, in connection with an assignment to an Affiliate under Section 16.2), in both cases (a) and (b), consistently applied.

1.2 "**Acquiring Entity**" means a Third Party that merges or consolidates with or acquires a Party, or to which a Party transfers all or substantially all of its assets to which this Agreement pertains.

1.3 "**Active Ingredient**" means the clinically active material(s) that provide pharmacological activity in a pharmaceutical product (excluding formulation components such as coatings, stabilizers, excipients or solvents, adjuvants or controlled release technologies).

1.4 "**Affiliate**" means, with respect to a Person, any other Person controlling, controlled by or under common control with such Person, for so long as such control exists. For purposes of this Section 1.4 only, "control" means (a) direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of directors of such corporate entity or (b) the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such entity, whether through the ownership of voting securities, by contract or otherwise.

1.5 "**Applicable Laws**" means collectively all laws, regulations, ordinances, decrees, judicial and administrative orders (and any license, franchise, permit or similar right granted under any of the foregoing) and any policies and other requirements of any applicable Governmental Authority that govern or otherwise apply to a Party's activities in connection with this Agreement.

1.6 "**AssemblyBio Ancillary Trials**" means the Clinical Trials conducted to support the Regulatory Submissions for any Licensed Product, which include DDI studies, ADME studies, studies of a Licensed Product in certain subpopulations (*e.g.* renal or hepatic impairment studies) or certain safety Clinical Trials as may be required by the applicable Regulatory Authorities (*e.g.* thorough QT/QTc assessment studies).

1.7 "**AssemblyBio Collaboration IP**" means all Inventions that are owned solely by AssemblyBio pursuant to Section 14.1(a).

1.8 "**AssemblyBio IP**" means, collectively, AssemblyBio Know-How and AssemblyBio Patent Rights.

1.9 "**AssemblyBio Know-How**" means all Know-How, *except* to the extent excluded subject to Sections 5.5(b) and 5.5(c), which: (a) is Controlled by AssemblyBio or any of its Affiliates as of the Effective Date or during the Term of this Agreement, (b) is not generally known, and (c) is necessary or reasonably useful for the Development, Manufacture or

Commercialization of Licensed Products (excluding Other Components in any Combination Product) in the Field in the Territory, including all Know-How included as part of AssemblyBio Collaboration IP.

1.10 "**AssemblyBio Patent Rights**" means all Patent Rights which (a) are Controlled by AssemblyBio or any of its Affiliates as of the Effective Date or at any time during the Term and (b) are necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as patents) for the Development, Manufacture or Commercialization of Licensed Products (excluding Other Components in any Combination Product) in the Field in the Territory, including all Patent Rights in the Territory claiming Product-Specific IP, AssemblyBio's interest in the Joint Patent Rights and all other Patent Rights claiming AssemblyBio Collaboration IP.

1.11 "**BeiGene Collaboration IP**" means all Inventions that are owned solely by BeiGene pursuant to Section 14.1(a).

1.12 "**BeiGene IP**" means all Patent Rights and Know-How (*except* to the extent excluded subject to Section 5.5(b)) that (i) are Controlled by BeiGene as of the Effective Date or (ii) thereafter come into BeiGene's Control independent of this Agreement, and in each case, that are generated, used or applied by or on behalf of BeiGene or its Affiliates or sublicensees in the Development, Manufacture or Commercialization of Licensed Products. For clarity, "BeiGene IP" does not include Product-Specific IP.

1.13 "**BeiGene Patent Rights**" means all Patent Rights in the BeiGene IP.

1.14 "**Business Day**" means a day other than (a) a Saturday or Sunday, and (b) any other day on which banking institutions in San Francisco, California or Beijing, China are authorized or required by Applicable Laws to remain closed.

1.15 "**Calendar Quarter**" means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; *provided* that the final Calendar Quarter shall end on the last day of the Term.

1.16 "**Calendar Year**" means the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) months commencing on January 1 and ending on December 31; *provided* that the final Calendar Year shall end on the last day of the Term.

1.17 "**cGMP**" means applicable current Good Manufacturing Practices, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820, (b) European Directive 2003/94/EC and Eudralex 4, (c) China Food and Drug Administration Ministry of Health Decree No. 79 for Good Manufacturing Practice for Drugs, effective as of March 1, 2011, (d) the principles detailed in the International Conference on Harmonization's Q7 guidelines, and (e) the Applicable Laws in any relevant country or region corresponding to (a) through (d) above, each as may be amended and applicable from time to time.

1.18 "**China**" means the People's Republic of China, which for the purposes of this Agreement shall exclude Hong Kong, Macau and Taiwan.

1.19 "**Clinical Data**" means, *except* to the extent excluded subject to Sections 5.5(b) and 5.5(c), (a) any and all data (together with all Clinical Trial reports and the results of analyses thereof) derived from or generated in any Clinical Trial, or (b) any and all pre-clinical or non-clinical data derived from or generated in any Development activities under this Agreement, in both cases (a) and (b), conducted by or on behalf of a Party.

1.20 "**Clinical Trial**" means any human clinical trial of a Licensed Product in the Field.

1.21 "**Clinical Trials Application**" means an application or submission to the competent Regulatory Authority for authorization to conduct a Clinical Trial in the applicable jurisdiction.

1.22 "**CMO**" means contract manufacturing organization.

1.23 "**Combination Product**" means a Licensed Product that is (a) sold in a form of a combination that contains or comprises a Licensed Compound and (i) one or more additional Active Ingredients (whether coformulated or copackaged or otherwise sold for a single price) other than a Licensed Compound, (ii) delivery device or component therefor, (iii) companion diagnostic related to any Licensed Compound, or (iv) product, process, service, or therapy other than the Licensed Compound (the products, devices, processes, services, and therapies described in the foregoing clauses (i) – (iv), each, an "**Other Component**"); or (b) defined as a "combination product" by the FDA pursuant to 21 C.F.R. §3.2(e) or its foreign equivalent, where such "combination product" is sold for a single price. Notwithstanding the foregoing, the License granted hereunder does not expand to Other Components of the Combination Product.

1.24 "**Commercialization**" or "**Commercialize**" means any and all activities directed to the offering for sale and sale of any Licensed Product, including (a) marketing, promoting, advertising, exhibiting, distributing, detailing, selling (and offering for sale or contracting to sell) or otherwise commercially exploiting a Licensed Product in the Field in the Territory (including importing and exporting activities in connection therewith); (b) order processing, handling of returns and recalls, booking of sales and transporting such Licensed Product for commercial sale; (c) the conduct of any post-approval Clinical Trials involving such Licensed Product; (d) interacting with Regulatory Authorities regarding the above; (e) seeking and obtaining pricing approvals and reimbursement approvals (as applicable) for that Licensed Product in the Territory; (f) any pharmacoeconomic studies relating to the Indication for which the applicable Licensed Product is being Developed; and (g) any investigator- or institution-sponsored studies. For clarity, Commercialization does not include activities directed to Development or Manufacture.

1.25 "**Commercially Reasonable Efforts**" means, (a) with respect to a Party's obligations or activities under this Agreement (other than those described in clause (b)), the carrying out of such obligations or activities with a level of effort and resources consistent with the commercially reasonable practices normally devoted [* * *] in accordance with Applicable Laws; and (b) with respect to the Development, Manufacture or Commercialization of the Licensed Compounds and Licensed Products by a Party, the carrying out of such activities with a

level of effort and resources consistent with the commercially reasonable practices normally devoted [* * *], taking into account all relevant factors, including but not limited to, [* * *].

1.26 "**Confidential Information**" of a Party (a "**Disclosing Party**") means, subject to Section 10.2, all Know-How, which is generated by or on behalf of such Disclosing Party under this Agreement and/or any other technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information that is disclosed by a Disclosing Party or its Affiliates to the other Party (a "**Receiving Party**") or its Affiliates pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidentiality Agreement) or which such Disclosing Party or any of its Affiliates or contractors has provided or otherwise made available to the Receiving Party, whether made available orally, in writing, or in electronic form, including (a) such Know-How comprising or relating to concepts, discoveries, Inventions, data, designs or formulae arising from this Agreement and (b) any unpublished patent applications disclosed hereunder. For purposes of clarity, unless excluded pursuant to Section 10.2, (i) all Clinical Data and results generated in any Joint Global Study shall be deemed Confidential Information proprietary to AssemblyBio, subject to the rights of BeiGene to use and reference such Clinical Data, without additional consideration, in accordance with Sections 5.9 and 6.3; (ii) all Inventions shall be deemed the Confidential Information of the owning Party as set forth in Section 14.1(a); (iii) any scientific, technical, manufacturing or financial information, including (*except* as set forth in (i) above) Clinical Data and information disclosed through an audit report, Commercialization report, Development report or other report, shall constitute Confidential Information of the Disclosing Party; (iv) any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party; and (v) the existence and terms of this Agreement shall be deemed Confidential Information of both of the Parties.

1.27 "**Control**" or "**Controlled**" means with respect to any material, Know-How, or intellectual property right (including Patent Rights), that a Party has the power (whether by ownership, license, or otherwise other than pursuant to this Agreement) to grant to the other Party access, a license, or a sublicense (as applicable) to the same on the terms and conditions set forth in this Agreement without violating any obligations of the granting Party to a Third Party. Notwithstanding the foregoing, a Party will not be deemed to "Control" any material, Know-How, or intellectual property right (including Patent Rights) that, prior to the consummation of the merger, consolidation or transfer making a Third Party an Acquiring Entity, is owned or in-licensed by such Third Party that becomes an Affiliate of such acquired Party after the Effective Date as a result of such acquisition transaction or that any Acquiring Entity subsequently develops without accessing or practicing any AssemblyBio IP or BeiGene IP unless (a) prior to the consummation of such acquisition transaction, such acquired Party or any of its Affiliates also owned or in-licensed such Patent Right or Know-How, or (b) the Know-How or Patent Rights owned or in-licensed by the applicable Third Party were not used in the performance of activities under this Agreement prior to the consummation of such acquisition transaction, but after the consummation of such acquisition transaction, such acquired Party or any of its Affiliates uses any such Patent Rights or Know-How in the performance of its obligations or exercise of its rights

under this Agreement, in each of which cases ((a) and (b)), such Patent Rights or Know-How will be "Controlled" by such Party for purposes of this Agreement.

1.28 "**Cover**" means, with respect to a Licensed Product in a particular country or region that the manufacture, use, sale or importation of such Licensed Product, as applicable, in such country or region would, but for the licenses granted herein, infringe a Valid Claim. Cognates of the word "Cover" shall have correlative meanings.

1.29 "**Develop**" or "**Development**" or "**Developing**" means all development activities for any Licensed Compound or Licensed Product that are directed to obtaining Regulatory Approval(s) of such Licensed Product and to support appropriate usage for such Licensed Product in the Field, including: (a) all non-clinical and preclinical testing and studies of such Licensed Product; (b) Clinical Trials; (c) toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies of such Licensed Product; (d) distribution of such Licensed Product for use in Clinical Trials (including placebos and comparators); (e) statistical analyses; (f) the preparation, filing and prosecution of any NDA for such Licensed Product in the Territory, with respect to Development activities conducted under the Territory Development Plan, and the preparation, filing and prosecution of any Biological License Application or New Drug Application (each as defined by the FDA) outside the Territory, with respect to Development activities conducted under the Global Development Plan; (g) all development activities directed to label expansion (including prescribing information) or obtaining Regulatory Approval for one or more additional Indications following initial Regulatory Approval; and (h) all development activities conducted after receipt of Regulatory Approval that are required or requested in writing by a Regulatory Authority as a condition of, or in connection with, obtaining or maintaining a Regulatory Approval; and (i) all regulatory activities related to any of the foregoing. For clarity, Development does not include activities directed to Manufacture or Commercialization.

1.30 "**Development and Regulatory Costs**" means all internal and external costs and expenses (including the cost of allocated FTEs at the FTE Rate) incurred by a Party and its Affiliates ("**Costs**") during the Term in connection with the Development of Licensed Compounds or Licensed Products in accordance with the Global Development Plan or Territory Development Plan:

(a) with respect to BeiGene, including, as applicable:

(i) all Costs incurred by BeiGene or its Affiliates in performing Development activities in or for the Territory (including [* * *]);

(ii) all Costs incurred by BeiGene or its Affiliates for Licensed Compounds or Licensed Products or any other materials (such as non-Party comparator drugs and placebo) reasonably required to be obtained or made for use in Clinical Trials of or related to a Licensed Compound or Licensed Product; and

(iii) all Costs incurred by BeiGene or its Affiliates associated with obtaining, maintaining and renewing Regulatory Submissions and Regulatory Approvals for a Licensed Product;

(b) with respect to AssemblyBio, including, as applicable:

(i) all Costs incurred by AssemblyBio or its Affiliates in performing Development activities in and for the Territory (including [* * *]); and

(ii) all Costs incurred by AssemblyBio or its Affiliates for Licensed Compounds or Licensed Products or any other materials (such as non-Party comparator drugs and placebo) reasonably required to be obtained or made for use in Clinical Trials of or related to a Licensed Compound or Licensed Product in and for the Territory (but excluding any such Costs taken into account in the calculation of Fully Burdened Manufacturing Costs);

in both cases (a) and (b), (x) as set forth in the Global Development Budget or the Territory Development Budget, (y) incurred in relation to activities expressly set forth in the Global Development Plan, the Territory Development Plan or this Agreement, and (z) evidenced by written records reasonably acceptable to the other Party; *provided* that any Costs [* * *] may be counted as Development and Regulatory Costs [* * *] (1) [* * *], (2) [* * *], and (3) [* * *]. For clarity, any external or Third Party costs are included in the Development and Regulatory Costs in the amount actually incurred without any markup. All Development and Regulatory Costs must be recorded in accordance with the applicable Accounting Standard, and either directly attributed to or fairly allocable to the Development activities of the Licensed Compounds and Licensed Products as conducted by the applicable Party.

1.31 "**Development Plan**" means the Global Development Plan, the Territory Development Plan or the ABI-H0731 Initial Development Plan.

1.32 "[* * *]" means, with respect to a [* * *], (a) the [* * *] of such [* * *] through (i) an [* * *] to a Third Party or (ii) an [* * *], with no further rights or role or ability to [* * *], directly or indirectly, with respect to such [* * *] such that neither the applicable Party nor its Affiliates are consulted with respect to, and do not otherwise participate in, [* * *] (other than those described in clauses (i) and (ii) above), or otherwise [* * *] with any Third Party, with respect to the [* * *] or the [* * *]; or (b) the complete [* * *] with respect to such [* * *]. For clarity, the right of the applicable Party to receive royalties, milestones or other payments in connection with [* * *] pursuant to sub-section (a) above, shall be permitted for any such [* * *]. When used as a verb, "[* * *]" and "[* * *]" means to cause a [* * *].

1.33 "[* * *]" means [* * *].

1.34 "**Exchange Act**" means the United States Securities Exchange Act of 1934, as amended.

1.35 "**FDA**" means the United States Food and Drug Administration or any successor entity thereto.

1.36 "**Field**" means the diagnosis, treatment, palliation or prevention of all indications, diseases and disorders in humans, *provided* that, with respect to the In-Licensed Patent Rights, the "Field" will be limited to diagnosis and treatment of all indications, diseases and disorders in humans.

1.37 "**Finite Duration Therapy**" means any labelled Indication for the treatment of chronic HBV infection that [* * *].

1.38 "**First Commercial Sale**" means, with respect to any Licensed Product in any country or jurisdiction in the Territory, the first sale of such Licensed Product by BeiGene, its Affiliates, or sublicensees to a Third Party for distribution, use or consumption in such country or jurisdiction after obtaining Regulatory Approvals, as applicable, have been obtained for such Licensed Product in such country or jurisdiction; *provided*, that, the following shall not constitute a First Commercial Sale of a Licensed Product: (a) any sale to an Affiliate or sublicensee, (b) any use of a Licensed Product in Clinical Trials, pre-clinical studies or other research or Development activities, or (c) the [* * *].

1.39 "**FTE**" means, with respect to a person the equivalent of the work of one (1) employee full time for one (1) year (consisting of at least a total of [* * *] per year, excluding vacations and holidays). Overtime, work on weekends, holidays and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. No one person shall be permitted to account for more than one FTE.

1.40 "**FTE Rate**" means, (a) for any employee of BeiGene conducting Development activities, [* * *], and (b) for an employee of AssemblyBio, [* * *], in both cases (a) and (b), increasing by [* * *] each January 1st beginning on January 1, [* * *]. The FTE Rate for each Party includes fully burdened personnel costs (including taxes, benefits, overhead, general and administrative expenses, related capital expenditures, etc.).

1.41 "**Fully Burdened Manufacturing Cost**" means, with respect to any Licensed Product supplied by or on behalf of AssemblyBio to BeiGene hereunder, and as determined on a Calendar Quarter-by-Calendar Quarter basis:

(a) if such Licensed Product (or any precursor or intermediate thereof) is Manufactured by a Third Party manufacturer, (i) the [* * *] costs of such supply of such Licensed Product (or precursor or intermediate) incurred by AssemblyBio, to the extent specifically identifiable or reasonably allocated to the supply of such Licensed Product as determined in accordance with GAAP (including, but not limited to, [* * *], the costs [* * *] of such Licensed Product (including applicable [* * *])), and (ii) any internal or Third Party costs incurred by AssemblyBio in connection with such Manufacturing by such Third Party, including [* * *] at the FTE Rate, *provided*, that the costs described in this clause (ii) [* * *]; or

(b) if such Licensed Product (or any precursor or intermediate thereof) is Manufactured by AssemblyBio or its Affiliate, the actual, fully burdened documented and verifiable direct and indirect costs and expenses incurred and recorded in Manufacturing such Licensed Product "consisting solely of" (i) the cost of [* * *] (including any costs incurred by AssemblyBio for time spent by AssemblyBio personnel to [* * *], at the FTE Rate), [* * *], (ii) the reasonable allocation of [* * *], to such manufacturing operation (including the allocable costs of [* * *], if applicable, but excluding [* * *]; (iii) [* * *] (including [* * *] but excluding any allocation for [* * *]); (iv) [* * *]; (v) [* * *]; (vi) [* * *]; and (vii) [* * *], in each case ((i) through (vii)), to the extent allocable to the Manufacture of such Licensed Product as determined in accordance with GAAP.

1.42 "**GAAP**" means United States generally accepted accounting principles, consistently applied.

1.43 "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Trials, including, as applicable (a) as set forth in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) (the "**ICH Guidelines**") and any other guidelines for good clinical practice for trials on medicinal products in the Territory, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, (d) the PRC Good Clinical Practices for Pharmaceutical Products (药物临床试验质量管理规范), as released by China National Medical Products Administration in 2003 and latest updated in 2020, and (e) the equivalent Applicable Laws in the region in the Territory, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.44 "**Generic Product**" means, with respect to a Licensed Product in a particular region in the Territory, any pharmaceutical product that is being sold commercially by a Third Party in such region in the Territory without authorization by BeiGene (or its Affiliate or sublicensee), that (a) contains the same Active Ingredient(s) as a Licensed Product, (b) is determined to be bioequivalent to such Licensed Product in accordance with Applicable Laws, and (c) is approved for sale in such region under an abbreviated route of regulatory approval in such region similar to the Abbreviated New Drug Application, or under 505(b)(2) of the United States Federal Food, Drug and Cosmetic Act, in the U.S. and is sold under a Regulatory Approval granted to the selling Third Party in such region which authorization is based substantially on clinical data pertaining to such Licensed Product. For purposes of clarity, for regions in the Territory where no explicit generic regulations exist, the term Generic Product also shall mean any product that is authorized for sale by the applicable Regulatory Authority in such region by a Third Party that contains the same Active Ingredient(s) as a Licensed Product.

1.45 "**Global Commercialization Principles**" means, with respect to a Licensed Product, the written summary of the key principles and strategy for the Commercialization of such Licensed Product in the Field worldwide (including in the Territory) to be prepared by AssemblyBio and approved by the JCC in accordance with this Agreement, as such written summary may be amended, modified or supplemented by either Party and approved by the JCC in accordance with Section 3.3(b).

1.46 "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, (a) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the U.S. Food and Drug Administration, as defined in 21 C.F.R. Part 58, (b) the Good Laboratory Practices for Nonclinical Drug Research, as released by China National Medical Products Administration in 2017, and (c) the equivalent Applicable Laws in the Territory, each as may be amended and applicable from time to time.

1.47 "**Governmental Authority**" means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, or any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.48 "**HBV Core Protein**" means HBV core protein (Cp), a structural protein, typically 183 or 185 amino acids long, that self assembles to form the HBV viral capsid. The key mechanism which HBV Cp controls HBV replication is with specific packaging of viral pgRNA and HBV polymerase protein into a viral capsid to enable viral DNA replication.

1.49 "**Indication**" means a generally acknowledged disease or condition, a significant manifestation of a disease or condition, or symptoms associated with a disease or condition or a risk for a disease or condition. For clarity, all variants of a single disease or condition (*e.g.*, variants of colon cancer or variants of prostate cancer), whether classified by severity or otherwise, shall be treated as the same Indication for purposes of this Agreement.

1.50 "**Invention**" means any Know-How, composition of matter, article of manufacture or other subject matter, whether patentable or not, that is conceived or reduced to practice in the conduct of the Development, Manufacture, or Commercialization of a Licensed Product under this Agreement.

1.51 "**Joint Global Study**" means a global Clinical Trial or a set of global Clinical Trials of a Licensed Product which include Clinical Trial sites in and outside of the Territory.

1.52 "**Know-How**" means all technical information, know-how, data, inventions, discoveries, trade secrets, specifications, instructions, processes, formulae, methods, protocols, expertise and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them, and all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data relevant to any of the foregoing. For clarity, Know-How excludes Patent Rights and physical substances.

1.53 "**Licensed ABI-H0731 Product**" means any Licensed Product containing ABI-H0731 as an Active Ingredient.

1.54 "**Licensed ABI-H2158 Product**" means any Licensed Product containing ABI-H2158 as an Active Ingredient.

1.55 "**Licensed ABI-H3733 Product**" means any Licensed Product containing ABI-H3733 as an Active Ingredient.

1.56 "**Licensed Compound**" means AssemblyBio's proprietary compounds: ABI-H0731, ABI-H2158, and ABI-H3733 (collectively, the "**Listed Compounds**"), each with the structure as set forth on Exhibit 1.56, and [* * *].

1.57 "**Licensed Product**" means any pharmaceutical, formulation or dosage form containing any Licensed Compound, whether as its sole active ingredient or in combination with one or more other active ingredients, in final finished form.

1.58 "**Manufacture**" or "**Manufacturing**" means activities directed to process, analytical and formulation development, manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, or storage of the Licensed Compounds and Licensed Products (or any components or process steps involving the Licensed Compounds and Licensed Products), placebo, or comparator agent, as the case may be, including process development, qualification, and validation, scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing. For clarity, Manufacture does not include activities directed to Development or Commercialization.

1.59 "**NDA**" means a New Drug Application (as defined by the NMPA or other applicable Regulatory Authorities in the Territory), or any successor application for Regulatory Approval having substantially the same function, or its foreign equivalent for approval to market or sell a pharmaceutical product in the Territory.

1.60 "**Net Sales**" means the gross amount invoiced by BeiGene, its Affiliates or sublicensees (collectively, the "**Sellers**") for sales or other transfers of Licensed Product in *bona fide* arm's length transactions to a Third Party (including any Third Party distributors, collectively, the "**Buyers**"), less the following deductions, [* * *]:

(a) [* * *], to the extent such [* * *] are not attributable to other products or services of the Sellers that are unrelated to the sales and distribution of the Licensed Product;

(b) [* * *], to the extent not otherwise attributable to other products or services of the Sellers that are unrelated to the sales and distribution of the Licensed Product;

(c) [* * *];

(d) [* * *] to the extent relating to the Licensed Product [* * *] in accordance with the applicable Seller's Accounting Standard, [* * *];

(e) [* * *] allowed or paid for [* * *]; and

(f) [* * *], in each case to the extent not reimbursed.

Each of the foregoing deductions shall be determined as incurred in the ordinary course of business in type and amount consistent with good industry practice and in accordance with the applicable accounting requirements on a basis consistent with BeiGene's audited consolidated financial statements. In the case of any other sale [* * *], such as [* * *], of any Licensed Product, or part thereof, other than [* * *], Net Sales shall be calculated as above [* * *], defined as [* * *].

For purposes of this Agreement, a "sale" or "transfer" shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of Licensed Product at no charge (i) for academic research, preclinical, clinical, or regulatory purposes (including the use of a Licensed Product in Clinical Trials), (ii) [* * *], or (iii) to

physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry and which is reasonably proportional to the market for such Licensed Product), to the extent permitted under Applicable Laws in the Territory.

All deductions in clauses (a) through (f) above will be fairly and equitably allocated between such Licensed Product and other products of the Sellers, such that such Licensed Product does not bear a disproportionate portion of such deductions. Calculations of Net Sales will be in accordance with the applicable Seller's Accounting Standard, consistently applied across all products of such Seller and across periods. If a single item falls into more than one of the categories set forth in clauses (a)-(f) above, then such item may not be deducted more than once.

In the event that a Combination Product is sold in the Territory by or under the authority of BeiGene or its Affiliate or sublicensee, Net Sales for the Licensed Product included in such Combination Product shall be calculated by multiplying the Net Sales (as calculated above but based on the gross invoice price of the Combination Product) during the applicable reporting period by the fraction A/(A+B), where "A" is the average sales price of the Licensed Product sold separately, and "B" is the average sales price of the Other Components, in each case, in the Territory during the applicable reporting period. If sales of the Licensed Product sold separately and of the Other Components did not occur during the applicable reporting period, the respective average sales prices during the most recent reporting period in which sales of both occurred in the Territory shall be used. In the event that either or both of A or (and) B is (are) not available in the Territory, then Net Sales for purposes of determining royalty payments shall be [* * *].

1.61 "**NMPA**" means the National Medical Products Administration of China, and local counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

1.62 "[* * *]" means, with respect to a Licensed Product, the [* * *].

1.63 "**Patent Prosecution**" means activities directed to (a) preparing, filing and prosecuting applications (of all types) for any Patent Rights, (b) managing any interference, opposition, re-issue, reexamination, supplemental examination, invalidation proceedings (including *inter partes* or post-grant review proceedings), revocation, nullification, or cancellation proceeding relating to the foregoing, (c) deciding whether to abandon, extend or maintain Patent Rights, (d) listing in regulatory publications (as applicable), and (e) settling any interference, opposition, reexamination, invalidation, revocation, nullification or cancellation proceeding, but excluding the defense of challenges to such patent or patent application as a counterclaim in an infringement proceeding with respect to the particular patent or patent application, and any appeals therefrom. For purposes of clarity, "Patent Prosecution" will not include any other enforcement actions taken with respect to a patent or patent application.

1.64 "**Patent Rights**" means the rights and interests in and to issued patents and pending patent applications (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, substitutions, continuations, continuations-in-part, continued prosecution applications including requests for continued examination, divisional applications and renewals, and all letters patent or certificates of invention granted thereon, and all reissues, reexaminations, extensions (including pediatric exclusivity patent extensions), term restorations, renewals,

substitutions, confirmations, registrations, revalidations, revisions and additions of or to any of the foregoing, in each case, in any country or region.

1.65 "**Person**" means any individual, corporation, company, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

1.66 "**Phase 3 Clinical Trial**" means a controlled or uncontrolled human Clinical Trial of a Licensed Product that would satisfy the requirements of 21 CFR 312.21(c) or corresponding foreign regulations, regardless of whether such trial is referred to as a "phase 3 clinical trial" in the Global Development Plan or the Territory Development Plan.

1.67 "**Pricing and Reimbursement Approval**" means the later of (a) the approval, agreement, determination, or governmental decision establishing a price for the applicable Licensed Product that can be legally charged to consumers, if required in a given country or region for the Commercialization of such Licensed Product in such country or region; and (b) the approval, agreement, determination, or governmental decision establishing the level of reimbursement for such Licensed Product that will be reimbursed by Governmental Authorities, if either required or otherwise commercially beneficial in a given country or region for the Commercialization of such Licensed Product in such country or region.

1.68 "**Product-Specific IP**" means all Inventions that are made jointly by the Parties or solely by a Party that relate (a) to the composition of matter of, or a method of using or detecting, a Licensed Compound or a Licensed Product, or any companion or complementary diagnostic to a Licensed Product, or (b) to a method of manufacturing specific to a Licensed Product.

1.69 "**Regulatory Approval**" means all approvals from the relevant Regulatory Authority necessary to initiate marketing and selling a product (including Licensed Product) in any country or jurisdiction, excluding Pricing and Reimbursement Approvals.

1.70 "**Regulatory Authority**" means any applicable Governmental Authority with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, clinical testing or sale of a pharmaceutical product (including any Licensed Product), which may include the authority to grant the required Pricing and Reimbursement Approvals for such sale.

1.71 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Licensed Product in a region, other than a Patent Right (potentially including new clinical data exclusivity, orphan drug exclusivity, pediatric exclusivity, or rights similar thereto), in each case, that confers exclusive rights to BeiGene, its Affiliates or sublicensees, as applicable to Commercialize such Licensed Product in such region.

1.72 "**Regulatory Submissions**" means any filing, application or submission with any Regulatory Authority, including authorizations, approvals or clearances arising from the foregoing, including Regulatory Approvals and any Pricing and Reimbursement Approvals, as applicable, and all correspondence or communication with or from the relevant Regulatory

Authority, as well as minutes of any material meetings, telephone conferences or discussions with the relevant Regulatory Authority, in each case, with respect to a Licensed Product.

1.73 "[* * *]" means, with respect to a [* * *], to [* * *] the research, development, manufacturing and commercialization activities relating to such [* * *], [* * *] research, development and commercialization activities with respect to Licensed Products under this Agreement, including by ensuring that: (a) [* * *], as applicable, [* * *] or [* * *]; and (b) [* * *]; *provided*, that, in either case of (a) or (b), [* * *], solely in connection with [* * *].

1.74 "**Territory**" means China, Hong Kong, Taiwan, and Macau, with each considered a "region" for purposes of this Agreement.

1.75 "**Territory Commercialization Plan**" means, with respect to a Licensed Product, the written strategic and tactical plan for the Commercialization of such Licensed Product in the Field in the Territory to be prepared by BeiGene in accordance with this Agreement, as such written plan may be amended, modified or updated by BeiGene in accordance with Section 3.3(b).

1.76 "**Territory Only Case**" means, with respect to each of (a) Licensed ABI-H0731 Product, (b) Licensed ABI-H2158 Product, and (c) Licensed ABI-H3733 Product, a scenario where all registrational Clinical Trials for such Licensed ABI-H0731 Product, Licensed ABI-H2158 Product or Licensed ABI-H3733 Product (as applicable) after the Effective Date for the purpose of obtaining the initial Regulatory Approval in the Territory are conducted within the Territory. With respect to the Licensed ABI-H0731 Product, the specific design of the Territory Only Case is set forth in the ABI-H0731 Initial Development Plan, as may be updated in accordance with Section 5.2(c).

1.77 "[* * *]" means [* * *].

1.78 "**Third Party**" means any Person other than a Party or an Affiliate of a Party.

1.79 "**United States**" or "**US**" means the United States of America and its territories and possessions.

1.80 "**Upstream License**" means that certain Exclusive License Agreement by and between AssemblyBio and Indiana University Research and Technology Corporation ("**IURTC**"), dated as of September 3, 2013, as may be amended.

1.81 "**USD**" means United States dollars.

1.82 "**Valid Claim**" means any claim of (a) an issued and unexpired patent or (b) a pending patent application, in each case included within the AssemblyBio Patent Rights; *provided* that such claim has not been abandoned, revoked or held unenforceable, invalid or unpatentable by a court or other government body of competent jurisdiction with no further possibility of appeal and which claim has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise; *provided* that, if a pending patent application has been pending for at least [* * *] years from its earliest claimed priority date, then such corresponding claim in such pending patent application will not be deemed to be a Valid Claim unless and until it subsequently issues.

1.83 Additional Definitions. The following table identifies the location of definitions set forth in various Sections of this Agreement:

Definition	**Section**
ABI-H0731 Initial Development Plan	5.2(c)
Accounting Firm	9.10(b)(i)
Agreement	Preamble
Agreement Payments	9.11(a)
Alliance Manager	3.1
Anti-Corruption Laws	12.7(a)(i)
Applicable Upstream License Provisions	2.8
AssemblyBio	Preamble
AssemblyBio Ancillary Trials Budget	5.5(c)
AssemblyBio Indemnitee(s)	13.1
AssemblyBio Publication	11.1(d)
AssemblyBio Veto Right	3.2(f)(i)
Audited Party	9.10(b)(i)
Auditing Party	9.10(b)(i)
BeiGene	Preamble
BeiGene Collaboration Patent Rights	14.3(a)
BeiGene Development Report	5.8
BeiGene Election	5.2(d)(ii)
BeiGene Indemnitees	13.2
BeiGene Publication	11.1(c)
BeiGene Veto Right	3.2(f)(ii)
Breach Notification	15.2(c)(i)
Claims	13.1
Clinical Supply Agreement	7.2(a)
Commercial Supply Agreement	7.2(b)
Commercialization Milestone Event	9.3
Commercialization Milestone Payment	9.3
Competing Product	2.6(a)
Confidentiality Agreement	16.15
Continuing Technology Transfer	4.1
Development Cost Cap	5.4(a)
Development Milestone Event	9.2
Development Milestone Payment	9.2
Disclosing Party	1.26
Dispute	16.6(a)
Effective Date	Preamble

Enforceable Patent Rights	14.3(b)
Ex-Territory Infringement	14.3(a)
Excluded Claim	16.6(e)
Executive Officers	3.2(f)
Existing Regulatory Materials	12.2(o)
Expert	16.7(c)
Expert Dispute	16.7(a)
Expert Resolution Notice	16.7(b)
[* * *]	9.2
Global Brand Elements	8.4(c)
Global Development Budget	5.2(a)
Global Development Plan	5.2(a)
Global Publication Strategy	11.1(a)
ICH Guidelines	1.43
In-Licensed Patent Rights	2.8
Indemnified Party	13.3
Indemnifying Party	13.3
Initial Technology Transfer	4.1
Initiation	9.2
JAMS	16.6(a)
JCC	3.3(b)
JDC	3.3(a)
JGS Territory Extra Costs	5.4(c)
JGS Territory Extra Patients	5.4(c)
JMC	3.3(c)
Joint COGM Improvements	7.2(d)(i)
Joint Collaboration IP	14.1(a)
Joint Patent Rights	14.1(c)(ii)
JSC	3.2(a)
License	2.1
Losses	13.1
New Development Proposal	5.5(a)
Notice of Dispute	16.6(a)
Party/Parties	Preamble
Patient Enrollment Guardrail	5.2(b)
Pharmacovigilance Agreement	6.4
Product Infringement	14.3(a)
Product Marks	14.8
Public Official	12.7(d)
Publication	11.1(d)

Receiving Party	1.26
Representatives	12.7(a)
[* * *]	[* * *]
Review Period	11.1(c)
Royalty Term	9.6(b)
Rules	16.6(a)
Scheduled Patent Rights	12.2(a)
SEC	11.4(c)
Securities Regulators	11.4(c)
Standstill Period	16.1
Subcommittees	3.3(d)
Taxes	9.11(a)
Technology Transfer	4.1
Term	15.1
Territory Clinical Trials	5.3(b)
Territory Development Budget	5.3(a)
Territory Development Plan	5.3(a)
Territory Only Case Budget	5.4(d)
Territory-Related Clinical Trials	5.3(b)
Territory-Specific Clinical Trials	5.3(b)
Third Party License	14.5
Unilateral Development Activity	5.5(b)
Upfront Payment	9.1

1.84 Interpretation. The captions and headings to this Agreement are for convenience only and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. In the event of any conflict between the main body of this Agreement and any Exhibit hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”; (b) the word “day” or “year” means a calendar day or year unless otherwise specified; (c) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (e) the words “shall” and “will” have interchangeable meanings for purposes of this Agreement; (f) the word “or” shall have the inclusive meaning commonly associated with “and/or”; (g) provisions that require that a Party, the Parties or a committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (h) words of any gender include the other gender; (i) words using the singular or plural number also include the plural or singular number, respectively; (j)

references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; and (k) neither Party or its Affiliates shall be deemed to be acting "under authority of" the other Party.

ARTICLE 2
LICENSE

2.1 License Grant to BeiGene. Subject to the terms and conditions of this Agreement and the terms and conditions of the Upstream License set forth on Exhibit 2.1, AssemblyBio hereby grants to BeiGene an exclusive (subject to AssemblyBio's retained rights as set forth in Section 2.3), royalty-bearing license, with the right to grant sublicenses solely in accordance with Section 2.2, under the AssemblyBio IP to (a) Develop and Commercialize Licensed Products in the Field in the Territory, and (b) if applicable, to conduct any Territory-Related Clinical Trials in accordance with Section 5.3(b) (the "**License**"). For clarity, the License does not include any right for BeiGene to Manufacture the Licensed Product, unless BeiGene takes on the Manufacturing of the Licensed Product pursuant to Sections 7.2(d)(i) or 7.3.

2.2 Right to Sublicense.

(a) Subject to the terms and conditions of this Agreement (including the Applicable Upstream License Provisions and other terms and conditions of the Upstream License as set forth in Exhibit 2.1), BeiGene shall have the right to grant sublicenses under the License through multiple tiers: (i) to its Affiliates, *provided* that such sublicense shall automatically terminate if such sublicensee ceases to be an Affiliate of BeiGene; (ii) subject to Section 5.10, to contract research organizations, distributors and other Third Party subcontractors for the sole purpose of performing BeiGene's obligations hereunder, on BeiGene's behalf, with respect to the Development and Commercialization (or Manufacturing, in the event BeiGene takes on the Manufacturing of the Licensed Product pursuant to Sections 7.2(d)(i) or 7.3) of Licensed Products in the Field in the Territory, in each case as is set forth in the Global Development Plan, Territory Development Plan or Territory Commercialization Plan; and (iii) to any other Third Party with respect to the Development and/or Commercialization of Licensed Products in the Field in the Territory, subject to AssemblyBio's prior written consent, not to be unreasonably withheld, conditioned or delayed. For purposes of clarity, BeiGene shall have the right, in connection with the grant of a sublicense to any Third Party pursuant to Section 2.2(a)(ii) or (iii), to transfer to such Third Party such quantities of Licensed Compound as is reasonably necessary for such Third Party to conduct Development and/or Commercialization activities in accordance with the sublicense grant.

(b) Each sublicense shall be subject to a written agreement that is consistent with the terms and conditions of this Agreement, and BeiGene shall ensure that its sublicensees comply with the terms and conditions of this Agreement. BeiGene shall include in each sublicense agreement an obligation of the applicable sublicensee to cease all activities with respect to Licensed Products if BeiGene terminates such sublicense agreement or if AssemblyBio terminates this Agreement. BeiGene will remain directly responsible for all its obligations under this Agreement, regardless of whether any such obligation is delegated or sublicensed to any of its Affiliates or sublicensees. Any act or omission of a sublicensee of BeiGene will be considered as an act or omission by BeiGene hereunder. In the event of any material breach by any such

sublicensee of any agreement entered into by BeiGene pursuant to Section 2.2(a) that would be a material breach of this Agreement by BeiGene, BeiGene shall [* * *]. BeiGene shall provide AssemblyBio with written notice of any proposed sublicense (including the identity of the sublicensee, a summary of the activities that are sublicensed and the region in which such rights have been sublicensed) and, to the extent the sublicense agreement is executed pursuant to Section 2.2(a)(iii), BeiGene shall provide AssemblyBio with a true and complete copy of such sublicense agreement within [* * *] after it becomes effective, subject to BeiGene's right to redact any confidential or proprietary information contained therein that is not necessary for AssemblyBio to determine compliance with this Agreement, and if such agreement is not in English, a certified translation into English thereof within [* * *] after the execution of such sublicense agreement.

2.3 Retained Rights. Notwithstanding the exclusive nature of the License, AssemblyBio expressly retains the rights to use the AssemblyBio IP in the Field in the Territory in order to (a) perform its obligations under this Agreement, (b) to conduct research and Development activities that are assigned to AssemblyBio under the Global Development Plan or otherwise to the extent expressly permitted by Sections 5.1(c), 5.5(b) and 5.5(c) of this Agreement, (c) to Develop the Licensed Products in the Territory to support the Development or Commercialization outside of the Territory (only to the extent such Development would not reasonably be expected to materially adversely impact BeiGene's Development or Commercialization activities of the Licensed Products in the Field in the Territory under this Agreement), and (d) to Manufacture Licensed Product in the Territory, in each case whether directly or through its Affiliates, licensees or contractors. For clarity, AssemblyBio retains the exclusive right to practice, license and otherwise exploit the AssemblyBio IP outside the scope of the License.

2.4 License Grants to AssemblyBio. Subject to the terms and conditions of this Agreement, BeiGene hereby grants to AssemblyBio a non-exclusive, fully-paid, royalty-free (except as set forth in Section 15.3(b)), perpetual, irrevocable, and sublicensable (through multiple tiers) license under the BeiGene IP, BeiGene Collaboration IP and BeiGene's interest in the Joint Collaboration IP solely (a) to Develop, Manufacture, and Commercialize Licensed Products outside the Territory and (b) to conduct any activities within AssemblyBio's retained rights set forth under Section 2.3 in the Territory.

2.5 No Implied Licenses; Negative Covenant. Except as expressly set forth herein, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, under any trademarks, Patent Rights or patent applications of the other Party. BeiGene shall not, and shall not permit any of its Affiliates or sublicensees to, practice any AssemblyBio IP outside the scope of the License.

2.6 Non-Compete.

(a) **Non-Compete Obligations of BeiGene**. Subject to Section 2.7 and except as otherwise agreed by the Parties, during the Term, BeiGene shall not [* * *] Commercialize any pharmaceutical product that [* * *] (each a "**Competing Product**") in the Territory, other than Licensed Products in accordance with this Agreement.

(b) **Non-Compete Obligations of AssemblyBio**. Subject to Section 2.7 and except as otherwise agreed by the Parties, during the Term, AssemblyBio shall not [* * *]

Commercialize any Competing Products in the Territory, other than Licensed Products in accordance with this Agreement.

2.7 [* * *]. Notwithstanding Section 2.6, if at any time during the Term:

(a) a Party or any of its Affiliates [* * *] through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction), such acquisition, and the [* * *] thereafter, shall not constitute a breach of [* * *] if such Party or such Affiliate, as applicable, (i) [* * *] such [* * *] within [* * *] of closing of the acquisition and, at all times prior to such [* * *], [* * *] such [* * *], or (ii) with the consent of the other Party, agrees to [* * *]; or

(b) a Third Party that is (at the time of such acquisition) [* * *] acquires a Party (whether by merger or acquisition of all or substantially all of the stock or of all or substantially all of the assets of such Party or of any operating or business division of such Party or similar transaction), such acquisition, and the [* * *] by such relevant acquiring Third Party, as the case may be, or any of its Affiliates, shall not constitute a breach of [* * *]; *provided* that (i) such acquiring Third Party at all times [* * *] and (ii) to the extent that AssemblyBio is the Party being acquired, then [* * *], solely to the extent reasonably necessary to (x) [* * *] or (y) [* * *]; *provided* that, in each case (x) and (y), [* * *].

2.8 Upstream License. BeiGene acknowledges and agrees that (a) AssemblyBio obtained the rights to certain AssemblyBio Patent Rights under the Upstream License (the "**In-Licensed Patent Rights**"); and (b) the License granted by AssemblyBio to BeiGene under Section 2.1 with respect to such In-Licensed Patent Rights constitutes a sublicense under the Upstream License. BeiGene shall comply with the terms and conditions of the Upstream License set forth in Exhibit 2.8 (the "**Applicable Upstream License Provisions**"). The Applicable Upstream License Provisions and other terms and conditions of the Upstream License as set forth in Exhibit 2.1 and Exhibit 14.6 shall be considered an integral part of the terms and conditions of this Agreement.

ARTICLE 3
GOVERNANCE

3.1 Alliance Managers. Each Party shall appoint an individual, who is an employee of such Party, to act as its alliance manager under this Agreement [* * *] after the Effective Date (the "**Alliance Manager**"). The Alliance Managers shall: (a) serve as the primary points of contact between the Parties for the purpose of providing the other Party with information on the progress of a Party's activities under this Agreement; (b) be responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, *provided* that all communications between the Parties shall be in English; (c) facilitate the prompt resolution of any disputes; and (d) attend JSC (as a non-voting participant), JDC, JMC, JCC and other Subcommittee meetings. An Alliance Manager may also bring any matter to the attention of the JSC, JDC, JMC, JCC or any other Subcommittee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may replace its Alliance Manager at any time upon written notice to the other Party.

3.2 Joint Steering Committee.

(a) **Formation**. No later than [* * *] following the Effective Date, the Parties shall establish a joint steering committee (the "**JSC**") to (i) monitor and coordinate the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory and the Development and Manufacture of Licensed Products pursuant to the Global Development Plan outside of the Territory and (ii) provide a forum for AssemblyBio to provide updates with respect to the Commercialization of Licensed Products outside of the Territory to the extent necessary and useful for BeiGene in its Commercialization of Licensed Products in the Field in the Territory. The JSC will be composed of an equal number of representatives from each Party and a minimum of three (3) representatives of each Party, with (x) at least two (2) representatives of each Party that have direct knowledge and expertise in the development, manufacture and commercialization of biopharmaceutical products, and (y) at least one representative of each Party holding the position of vice president or above in such Party. Each representative to the JSC shall be an employee of the applicable Party, unless otherwise agreed by both Parties.

(b) **Role**. The JSC shall:

(i) set the strategic direction of, and encourage and facilitate ongoing communication between the Parties with respect to, the Development, Manufacture and Commercialization of Licensed Products;

(ii) provide a forum for the discussion of the Parties' activities under this Agreement;

(iii) review and discuss the overall strategy for the Development, Manufacture, and Commercialization of Licensed Products in the Field in the Territory;

(iv) establish and oversee the JDC, JCC, JMC and other Subcommittees as necessary or advisable to further the purpose of this Agreement, and review, discuss and try to resolve any unresolved disputes from the JDC, JCC, JMC and other Subcommittees;

(v) review and discuss any updates provided by AssemblyBio regarding AssemblyBio Know-How pursuant to Section 4.1;

(vi) review and discuss each BeiGene Development Report, the status, progress and results of Development activities of the Licensed Products and the related costs pursuant to Section 5.8;

(vii) review and discuss any potential harmful actions brought to its attention by either Party pursuant to Section 6.6;

(viii) review and discuss any Commercialization report submitted by BeiGene pursuant to Section 8.3;

(ix) review, discuss and adopt the Global Publication Strategy and any amendments thereto pursuant to Section 11.1(a); and

(x) perform such other functions as expressly set forth in this Agreement or allocated to the JSC by the Parties' written agreement.

(c) **Limitation of Authority**. The JSC shall only have the powers expressly assigned to it in this Article 3 and elsewhere in this Agreement and shall not have the authority to: (i) modify or amend the terms and conditions of this Agreement; (ii) waive either Party's compliance with the terms and conditions of this Agreement; or (iii) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

(d) **Meetings**. The JSC shall hold meetings at such times as it elects to do so, but shall meet no less frequently than [* * *] per Calendar Year. In addition, special meetings of the JSC may be convened by either Alliance Manager upon not less than [* * *] (or, if such meeting is proposed to be conducted by teleconference, as soon as reasonably practicable) written notice to the other Alliance Manager. The JSC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communication method, or (no more than [* * *]) in person at locations selected alternatively by AssemblyBio and BeiGene or such other location as the Parties may agree. Each Party shall bear its own expenses related to participation in and attendance at such meetings by its respective JSC representatives. The Alliance Managers shall jointly prepare and circulate minutes for each JSC meeting within [* * *] of each such meeting and shall ensure that such minutes are reviewed and approved by their respective companies within [* * *] thereafter. Communications between the Parties pursuant to the JSC meetings shall be in English.

(e) **Non-Member Attendance**. Each Party may from time to time invite a reasonable number of participants, in addition to its representatives, to attend a meeting of the JSC (in a non-voting capacity), JDC, JCC, JMC or other Subcommittee in the event that the planned agenda for such JSC, JDC, JCC, JMC or Subcommittee meeting would require such participants' expertise; *provided* that if either Party intends to have any Third Party (including any consultant) attend such a meeting, such Party shall provide prior written notice to the other Party, shall obtain approval from such other Party for such Third Party to attend (such approval not to be unreasonably withheld, conditioned or delayed), and shall ensure that such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement.

(f) **Decision-Making**. All decisions of the JSC shall be made by consensus, with each Party's representatives having, collectively, one vote. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the JSC, the JSC cannot reach consensus as to such matter within [* * *] after such matter was brought to the JSC for resolution, such matter shall be referred to the Chief Executive Officer of AssemblyBio (or an executive officer of AssemblyBio designated by the Chief Executive Officer of AssemblyBio who has the power and authority to resolve such matter) and the Chief Executive Officer of BeiGene (or an executive officer of BeiGene designated by the Chief Executive Officer of BeiGene who has the power and authority to resolve such matter) (collectively, the "**Executive Officers**") for

resolution. If the Executive Officers cannot resolve such matter within [* * *] after such matter has been referred to them, then:

(i) **BeiGene Final Decision-Making Authority**. Subject to Section 3.2(f)(ii), BeiGene shall have the final decision-making authority for matters within the scope of the JSC's decision-making authority with respect to (A) any [* * *] for Licensed Products solely in the Field in the Territory [* * *], including [* * *], (B) all [* * *], including approval of the [* * *], and, with respect to Licensed Products, further including [* * *], in each case solely in the Field in the Territory, and (C) all [* * *] leading up to and including the [* * *], solely for Licensed Products in the Field from Regulatory Authorities in the Territory; *provided that* BeiGene shall not exercise its final decision making authority to take any action that would be reasonably expected to (x) [* * *], or (y) [* * *], in both cases (x) and (y), without AssemblyBio's prior consent (such consent not to be unreasonably withheld, conditioned or delayed) (AssemblyBio's right to veto matters set forth under clauses (x) and (y), "**AssemblyBio Veto Rights**").

(ii) **AssemblyBio Final Decision-Making Authority**. Subject to Section 3.2(f)(i), AssemblyBio shall have the final decision-making authority for matters within the scope of the JSC's decision-making authority with respect to (A) whether the Parties will [* * *] for the Licensed Products, (B) any [* * *], including any [* * *], (C) the approval of the [* * *] and any updates thereto, (D) the approval of [* * *] or any updates thereto, and (E) any [* * *] matters of the Licensed Compounds and Licensed Products, *except* for [* * *]; *provided* that, AssemblyBio shall not exercise its final decision-making authority in a manner that would be reasonably expected to: (x) [* * *], or (y) [* * *], in both cases (x) and (y), without BeiGene's prior consent (such consent not to be unreasonably withheld, conditioned or delayed) (BeiGene's right to veto matters set forth under clauses (x) and (y), "**BeiGene Veto Rights**"). For clarity, AssemblyBio retains sole discretion and final decision-making authority with respect to (1) any Development or Commercialization activities in relation to the Licensed Compounds and Licensed Products outside of the Territory, and (2) the Development of all Licensed Products before the Initiation of Phase 3 Clinical Trial thereof, including such Development activities in the Territory pursuant to Section 5.1(c). Notwithstanding the foregoing, as AssemblyBio exercises its sole discretion and final decision-making authority with respect to any Development or Commercialization activities in relation to the Licensed Compounds and Licensed Products outside of the Territory, if [* * *], then [* * *].

(iii) **No Change; Status Quo**. Neither Party shall have final decision making authority with respect to: (A) the number of patients to be enrolled in the Territory for any Joint Global Study in excess of [* * *] of the worldwide patients to be enrolled pursuant to Section 5.2(b), subject to the Patient Enrollment Guardrail thereunder; (B) whether to approve any Global Development Budget or Territory Development Budget for the Licensed ABI-H0731 Products pursuant to Section 5.2(c) that [* * *]; (C) any approval of a New Development Proposal under Section 5.5(a); (D) any Joint COGM Improvements (which shall require amendment of this Agreement); (E) the transfer of some or all Manufacturing responsibilities of Licensed Compounds and Licensed Products in the Territory to BeiGene pursuant to Section 7.2(d)(i); and (F) whether [* * *]. All matters set forth in the foregoing clauses ((A) through (F)) must be decided by unanimous agreement of the Parties in order to take any action or adopt any change from the then-current *status quo*.

3.3 Sub-Committees.

(a) **Joint Development Committee**. Within [* * *] after the Effective Date, the Parties shall establish a joint development committee (the "**JDC**") to (i) review, discuss, coordinate and share information regarding the Development of Licensed Products in the Territory or outside the Territory pursuant to the Global Development Plan; (ii) review, discuss, and share information regarding the Development of Licensed Products outside of the Territory; (iii) review, discuss, coordinate and share information regarding the progress of the Regulatory Approvals and Regulatory Submissions for Licensed Products in the Territory; (iv) review, discuss and approve the Territory Development Plan and Global Development Plan and any amendments thereto; (v) agree to the proportion of patients in any Joint Global Study to be included from the Territory pursuant to Section 5.2(b); (vi) review, discuss and determine the path forward for the joint Development of the Licensed ABI-H2158 Products and Licensed ABI-H3733 Products under Section 5.2(d), (vii) coordinate regarding the reimbursement of the JGS Territory Extra Costs under Section 5.4(c); (viii) review, discuss and determine whether to approve any New Development Proposal pursuant to Section 5.5(a); (ix) review updates regarding Clinical Trials conducted pursuant to the Global Development Plan or the Territory Development Plan pursuant to Section 6.2; and (x) perform such other functions as expressly set forth in this Agreement or allocated to the JDC by the Parties' written agreement.

(b) **Joint Commercialization Committee**. Not later than [* * *] prior to the anticipated date of the filing of the first application for Regulatory Approval for a Licensed Product in the Territory, the Parties shall establish a joint commercialization committee (the "**JCC**") to: (i) review, discuss, coordinate, share information regarding, and approve the Global Commercialization Principles and the Territory Commercialization Plan and amendments thereto; (ii) review, discuss, coordinate, and share information regarding the progress of the Commercialization of Licensed Products in the Territory; (iii) review, discuss, coordinate, and share information regarding commercial issues relevant to the Commercialization of Licensed Products in the Territory and AssemblyBio's Commercialization of Licensed Products outside of the Territory and global harmonization of such activities; (iv) review and discuss any Commercialization report submitted by BeiGene pursuant to Section 8.3; (v) review and discuss any pricing matters of the Licensed Products in and outside of the Territory pursuant to Section 8.4(b); (vi) review and discuss the branding strategy for the Licensed Products in the Territory pursuant to Section 8.4(c); and (vii) perform such other functions as expressly set forth in this Agreement or allocated to the JCC by the Parties' written agreement.

(c) **Joint Manufacturing Committees**. Not later than [* * *] after the Effective Date, the Parties shall establish a joint manufacturing committee (the "**JMC**") to: (i) review and discuss Manufacturing of Licensed Compounds and Licensed Products, including the Fully Burdened Manufacturing Cost; (ii) review, discuss and approve any Joint COGM Improvements pursuant to Section 7.2(d); (iii) review and discuss potential transfer of Manufacturing activities to the Territory pursuant to Section 7.3 (*provided*, that such transfer shall require the approval of the Parties, rather than the JMC, pursuant to Section 7.3); and (iv) perform such other functions as expressly set forth in this Agreement or allocated to the JMC by the Parties' written agreement.

(d) **Subcommittees and Working Groups**. The JSC may create, when advisable, other subcommittees or working groups (such as, for example, a joint project team in charge of day-to-day communication and operation of the Development activities in the Territory),

comprised of representatives of each Party having qualifications and experience relevant to a productive dialogue on the subject matter of each such subcommittee (collectively with the JDC, JCC and JMC, the "**Subcommittees**").

(e) **Subcommittee Representatives**. Each Party shall appoint two (2) representatives to each Subcommittee, each of whom is an officer or employee of the applicable Party having sufficient knowledge regarding the topics within the jurisdiction of such Subcommittee with respect to the Territory.

(f) **Subcommittee Meetings**. The Subcommittees will meet with the frequency and in the manner (in person or otherwise) of the JSC or such other frequency or manner as the JSC shall determine.

(g) **Subcommittee Decision Making**. Each Subcommittee and its activities shall be subject to the oversight of, and shall report to, the JSC, and the JSC shall resolve all disputes that arise within the Subcommittee within [* * *] after any such matter is brought to the JSC for resolution, except regarding the JDC's decision on the path forward for the joint Development of the Licensed ABI-H2158 Products and Licensed ABI-H3733 Products under Section 5.2(d)(i), which shall be referred to the Executive Officers of the Parties for resolution directly if JDC is unable to reach an agreement pursuant to Section 5.2(d). In no event shall the authority of the Subcommittees exceed the authority of the JSC. Each Party shall be responsible for all of its own expenses of participating in the Subcommittees.

3.4 Discontinuation of JSC and Subcommittees. The JSC shall continue to exist until the Parties mutually agree to disband the JSC. Once the JSC is disbanded, the JSC shall have no further obligations under this Agreement and, thereafter, the Alliance Managers shall be the points of contact for the exchange of information under this Agreement and decisions of the JSC shall be decisions between the Parties, subject to the other terms and conditions of this Agreement. The Subcommittees shall disband upon the disbandment of the JSC or earlier, as determined by the JSC.

ARTICLE 4
TECHNOLOGY TRANSFER

4.1 Technology Transfer. Within [* * *] after the Effective Date, AssemblyBio will provide and transfer to BeiGene [* * *] the AssemblyBio Know-How that exists on the Effective Date and was not previously provided to BeiGene by providing copies or samples of relevant documentation, materials and other embodiments of such AssemblyBio Know-How, including data within reports, and electronic files, that exist on the Effective Date (the "**Initial Technology Transfer**"). Thereafter, during the Term, AssemblyBio shall (a) at each meeting of the JSC (and, in any event, on [* * *] if any JSC meeting is not held in a particular [* * *]), provide BeiGene with a summary of additional AssemblyBio Know-How, if any, developed since the last meeting of the JSC, (b) transfer any such AssemblyBio Know-How to BeiGene promptly following BeiGene's reasonable request, and (c) provide BeiGene with reasonable access to AssemblyBio personnel involved in the research and Development of Licensed Products, either in-person at AssemblyBio's facility or by teleconference (the "**Continuing Technology Transfer**," and together with the Initial Technology Transfer, the "**Technology Transfer**"). For the avoidance of doubt, AssemblyBio's personnel shall not be obligated to travel to BeiGene's facilities, and

AssemblyBio's transfer obligations under this Section 4.1 shall apply solely to the extent the AssemblyBio Know-How is reasonably necessary to support BeiGene's Development and Commercialization of a Licensed Product in the Field in the Territory in accordance with this Agreement.

ARTICLE 5
DEVELOPMENT PROGRAM

5.1 Diligence and Responsibilities.

(a) BeiGene shall be responsible for the Development of the Licensed Products in the Field in the Territory in accordance with this Article 5. BeiGene shall use Commercially Reasonable Efforts to (i) Develop Licensed Products in the Field in the Territory in accordance with the Territory Development Plan and the Global Development Plan, and (ii) obtain Regulatory Approval and Pricing and Reimbursement Approval for Licensed Products in the Field in the Territory in accordance with the Territory Development Plan. BeiGene shall conduct such tasks in a timely, professional manner and in compliance with the Territory Development Plan and Global Development Plan, as applicable, and all Applicable Laws, including GLP, GCP and cGMP.

(b) AssemblyBio shall be responsible for the Development of the Licensed Products outside of the Territory. AssemblyBio shall use Commercially Reasonable Efforts to conduct the research and Development activities in or for the Territory that are assigned to AssemblyBio under the Global Development Plan. In addition, AssemblyBio may conduct research and Development activities in the Territory (i) to the extent permitted by Sections 5.1(c), 5.5(b) and 5.5(c) of this Agreement, or (ii) to support the Development or Commercialization outside of the Territory (to the extent such Development by AssemblyBio in the Territory would not [* * *]).

(c) Unless the Parties otherwise agree, AssemblyBio will have operational control over the Development of each Licensed Product before the Initiation of Phase 3 Clinical Trial for such Licensed Product, including such Development activities in the Territory, and shall be solely responsible for all costs and expenses of all such Development activities. For clarity, any phase 1 or phase 2 Clinical Trials for a Licensed Product conducted concurrently with or after the Initiation of a Phase 3 Clinical Trial for such Licensed Product will remain subject to the foregoing provision in this Section 5.1(c) after the Initiation of Phase 3 Clinical Trial of such Licensed Product.

5.2 Global Development Activities.

(a) **Global Development Plan**. With respect to each of Licensed ABI-H0731 Products, Licensed ABI-H2158 Products and Licensed ABI-H3733 Products, the Parties will discuss and decide through the JDC whether to jointly conduct global Development activities for such Licensed Products (including a Joint Global Study) that include Clinical Trial sites in the Territory, taking into account the feedback from the Regulatory Authorities in and outside the Territory, and with respect to Licensed ABI-H2158 Products and Licensed ABI-H3733 Products, subject to Section 5.2(d). If the Parties disagree regarding the foregoing, [* * *] regarding whether the Parties shall jointly conduct global Development activities for such Licensed Products (including a Joint Global Study), *provided* that the proposed Development activities to be

conducted in the Territory and the related study protocols are [* * *]. If the Parties agree to conduct any such joint global Development activities (including any Joint Global Study) or if [* * *] (subject to BeiGene Election under Section 5.2(d)(ii)), the Parties, through the JDC, will agree to a global clinical Development plan for such joint global Development activities, including a Clinical Trial protocol for any Joint Global Study (the "**Global Development Plan**" and, until the Global Development Plan is approved pursuant to this Section 5.2(a), all references in this Agreement to the Global Development Plan shall be deemed references to the ABI-H0731 Initial Development Plan). The Global Development Plan shall include (i) an outline of all such global Development activities (including all Clinical Trials) for Licensed Products to be conducted by either Party, (ii) details and timelines of the Development activities in the Territory assigned to BeiGene as part of a Joint Global Study (including the number of patients to be enrolled in the Territory for such Joint Global Study), (iii) unless otherwise agreed to by the Parties, the details and timelines of any other Development activities (including Clinical Trials) in the Territory assigned to BeiGene to support global Development of the Licensed Product, and (iv) a proposed budget for the Joint Global Study and other global Development activities set forth under the Global Development Plan (including any Costs incurred related to any start-up activities for any Phase 3 Clinical Trial) (the "**Global Development Budget**"). AssemblyBio will propose the initial draft of the Global Development Plan and submit to the JDC for its review, discussion and, solely with respect to the portion of the Global Development Plan that relates to the Territory or activities assigned to BeiGene, approval. From time to time, AssemblyBio may make and implement amendments to the then-current Global Development Plan, and may propose amendments to the Global Development Plan to include the other Licensed Compounds. To the extent such amendments relate to the Territory or activities assigned to BeiGene, AssemblyBio shall submit such proposed amendments to the JDC for review, discussion and approval. AssemblyBio shall [* * *] any comments provided by BeiGene with respect to the Global Development Plan and any amendments thereto to the extent related to the Territory or activities assigned to BeiGene. In [* * *] in relation to whether to conduct a Joint Global Study and designing study protocols under the Global Development Plan, AssemblyBio shall reasonably take into account [* * *].

(b) **Joint Global Study Patient Enrollment**. The portion of patients to be enrolled in the Territory for each Joint Global Study shall be mutually agreed to by the Parties and set forth in the applicable Global Development Plan (and in no event shall be less than [* * *] of all patients to be enrolled worldwide, unless the Parties otherwise agree), which allocation will be determined in a manner to maximize the speed and chance of success for such Joint Global Study. BeiGene will be responsible for the recruitment and enrollment of all patients in the Territory and the conduct of the portion of the Clinical Trial in the Territory that constitutes part of the Joint Global Study. Notwithstanding [* * *], in the event that AssemblyBio's proposed portion of patients allocated to the Territory for any Joint Global Study exceeds [* * *] of all patients to be enrolled worldwide, BeiGene has the right to veto such allocation above [* * *] of worldwide patients if, [* * *], in which case the Parties will discuss in good faith through the JDC and agree on any portion of patients above [* * *] of worldwide patients to be enrolled in the Territory by BeiGene for such Joint Global Study, and in the event the Parties cannot reach an agreement, the number of patients to be enrolled in the Territory shall be [* * *] of all patients to be enrolled worldwide (the "**Patient Enrollment Guardrail**").

(c) **ABI-H0731 Initial Development Plan**. The initial Development Plan for the Licensed ABI-H0731 Products is attached hereto as Exhibit 5.2(c) (the "**ABI-H0731 Initial Development Plan**"). The ABI-H0731 Initial Development Plan sets forth, among other things, [* * *]. Any global Development activities (including any Joint Global Study) in the ABI-H0731 Initial Development Plan shall be updated by the Parties pursuant to the process described in Section 5.2(a), and any Territory-specific Development activities in the ABI-H0731 Initial Development Plan will be updated pursuant to the process described in Section 5.3(a). The Global Development Budget and Territory Development Budget, as applicable, for the Licensed ABI-H0731 Products shall not [* * *], unless such Phase 3 Clinical Trial design is modified as contemplated by this Section 5.2(c) (i) [* * *], (ii) [* * *], or (iii) as otherwise agreed by the Parties.

(d) **Joint Development of Licensed ABI-H2158 Products and Licensed ABI-H3733 Products**.

(i) **Selection of Development Plan**. For each of Licensed ABI-H2158 Products and Licensed ABI-H3733 Products, promptly after the first end-of-phase 2 (EOP2) meeting between AssemblyBio and the applicable Regulatory Authority, the Parties shall discuss through the JDC the path forward for the joint Development of the Licensed ABI-H2158 Products or Licensed ABI-H3733 Products (as applicable), and shall discuss (A) whether to conduct a Territory-only Phase 3 Clinical Trial for such Licensed Products, including the study design, protocol, the number of patients to be enrolled for such Phase 3 Clinical Trial, and the related budget for such Development activities; and (B) (x) whether the Territory will be part of the Joint Global Study, and (y) if the Territory will be part of the Joint Global Study, the study design and protocol for the Territory-portion of such Joint Global Study, the number of patients to be enrolled for such Joint Global Study in the Territory (pursuant to Section 5.2(b)), and the related budget for such Development activities. If the JDC decides to move forward with the Territory-only Phase 3 Clinical Trial for such Licensed Products, such Development activities will be governed by a Territory Development Plan pursuant to Section 5.3(a) and subject to the cost sharing arrangement under Section 5.4. If the JDC decides to move forward with a Joint Global Study, such Development activities will be governed by a Global Development Plan pursuant to Section 5.2(a) and the Territory-portion of such Joint Global Study shall be subject to the cost sharing arrangement under Section 5.4. If the JDC cannot reach an agreement regarding the path forward for the joint Development of the Licensed ABI-H2158 Products or Licensed ABI-H3733 Products (as applicable) within [* * *] following the first EOP2 meeting between AssemblyBio and the applicable Regulatory Authority, such matter shall be referred to the Executive Officers of both Parties for resolution. All discussion between the Parties under this Section 5.2(d)(i) shall be conducted and all decisions related thereto shall be made in good faith. For clarity, AssemblyBio shall retain operational control and full discretion over any Development activities outside of the Territory (including any global study that does not include the Territory or any portion of a Joint Global Study that is outside of the Territory).

(ii) **BeiGene's Election**. If the Executive Officers of the Parties cannot agree upon a path forward for the joint Development of the Licensed ABI-H2158 Products or Licensed ABI-H3733 Products (as applicable) within [* * *] after such matter is referred to them pursuant to Section 5.2(d)(i), AssemblyBio shall have the final decision-making authority regarding such matter (which authority shall not be subject to BeiGene Veto Rights under Section 3.2(f)(ii)). If AssemblyBio decides to move forward with a Joint Global Study for such Licensed Products with patient enrollment in the Territory pursuant to Section 5.2(b), then BeiGene shall

have the option to, solely with respect to the Licensed ABI-H2158 Products or Licensed ABI-H3733 Products (as applicable): (A) conduct the Territory-portion of the Joint Global Study as proposed by AssemblyBio, or (B) terminate this Agreement with respect to the Licensed ABI-H2158 Products or Licensed ABI-H3733 Products (as applicable) immediately upon written notice to AssemblyBio (the election to terminate pursuant to this clause (B), the "**BeiGene Election**"). In the event BeiGene elects to conduct the Territory-portion of the Joint Global Study, the Parties will continue to collaborate on such Development activities pursuant to a Global Development Plan for the applicable Licensed Products in accordance with Section 5.2(a) and Section 5.2(b) and the Territory-portion of the Joint Global Study shall be subject to the cost sharing arrangement under Section 5.4. In the event BeiGene elects to exercise BeiGene Election, (1) this Agreement will be deemed terminated immediately with respect to the Licensed ABI-H2158 Products or Licensed ABI-H3733 Products (as applicable) upon written notice of such election by BeiGene to AssemblyBio, which notice shall be provided within [* * *] after the expiration of the foregoing [* * *] period; (2) BeiGene shall [* * *]; (3) ABI-H2158 or ABI-H3733 (as applicable) and such Licensed Compound's corresponding Licensed Products will cease to be a Licensed Compound, Listed Compound and Licensed Products under this Agreement, and, except as set forth under clause (4) below, will no longer be subject to terms and conditions of this Agreement (including the non-compete obligations under Section 2.6 and the payment obligations under Article 9); (4) Section 15.3 shall apply to ABI-H2158 or ABI-H3733 (as applicable) and such Licensed Compound's Licensed Products (to the extent applicable, except that, for clarity, such Licensed Products shall not be subject to [* * *] under Section 15.3(b)); and (5) BeiGene shall have no further rights or obligations related to ABI-H2158 or ABI-H3733 (as applicable) and such Licensed Compound's corresponding Licensed Products, and Exhibit 12.2(a) will be deemed to be updated to exclude the AssemblyBio Patent Rights that are solely related thereto. For clarity, in the event AssemblyBio decides to move forward with a Joint Global Study for the Licensed ABI-H2158 Products or Licensed ABI-H3733 Products (as applicable), BeiGene shall no longer have the option to instead conduct a Territory-only Phase 3 Clinical Trial for such Licensed Products but shall have the right to make the BeiGene Election.

5.3 Territory Development Activities.

(a) **Territory Development Plan**. Except for the activities allocated to BeiGene under the Global Development Plan pursuant to Section 5.2, all Development of Licensed Products in the Territory under this Agreement shall be conducted by BeiGene pursuant to a written development plan (as amended from time to time in accordance with this Section 5.3 and Section 3.3(a), the "**Territory Development Plan**" and, until the Territory Development Plan is approved pursuant to this Section 5.3(a), all references in this Agreement to the Territory Development Plan shall be deemed references to the ABI-H0731 Initial Development Plan). The Territory Development Plan shall include a proposed budget for the Development activities (including the Territory Clinical Trials) set forth under the Territory Development Plan (including any Costs incurred related to any start-up activities for any Phase 3 Clinical Trial) (the "**Territory Development Budget**"). AssemblyBio will propose the initial draft of the Territory Development Plan for the Licensed ABI-H2158 Products and Licensed ABI-H3733 Products and submit to the JDC for its review, discussion and approval. From time to time after the Effective Date, but not less than annually, either Party may propose amendments to the Territory Development Plan and submit such proposed updated or amended Territory Development Plan to the JDC for review, discussion and approval. Once approved by the JDC, the amended Territory Development Plan

shall become effective. For clarity, the Territory Development Plan and amendments thereto shall be consistent with the Global Development Plan, and the Global Development Plan shall take precedence in case of any conflict or inconsistency between the Territory Development Plan and the Global Development Plan.

(b) **Territory Clinical Trials**. In accordance with the Territory Development Plan, BeiGene shall be responsible for and be the sponsor of (i) all Clinical Trials in the Territory that are not part of the Joint Global Study nor part of AssemblyBio's retained right under Section 2.3 to conduct Development activities with respect to the Licensed Products (the "**Territory-Specific Clinical Trials**"), and (ii) all Clinical Trials in other Asian countries outside of the Territory that are required by Regulatory Authorities in the Territory (the "**Territory-Related Clinical Trials**," together with the Territory-Specific Clinical Trials, the "**Territory Clinical Trials**"). The Development and Regulatory Costs incurred by BeiGene for the Territory-Specific Clinical Trials will count towards the Development Cost Cap and be subject to Section 5.4. [* * *] of the Development and Regulatory Costs incurred by BeiGene for Development activities for countries outside of the Territory in relation to the Territory-Related Clinical Trials.

5.4 Development Costs Sharing.

(a) **Development Cost Cap**. BeiGene will be responsible for all Development and Regulatory Costs for the Development activities with respect to the Licensed Products in and for the Territory contemplated by the Global Development Plan and Global Development Budget or the Territory Development Plan and Territory Development Budget, as applicable, after the Effective Date (including the portion of Joint Global Studies being conducted in the Territory), up to an aggregate maximum of USD forty-five million ($45,000,000) (the "**Development Cost Cap**"). For clarity, except as provided under Section 5.5(c), costs and expenses incurred by AssemblyBio outside of the Territory are not within BeiGene's responsibility.

(b) **Development Costs Sharing Over Cap**. After BeiGene's total expenditure on Development and Regulatory Costs for the Territory reaches the Development Cost Cap, BeiGene and AssemblyBio will share all Development and Regulatory Costs incurred by both Parties in relation to Licensed Products in and for the Territory (including the portion of Joint Global Studies being conducted for Licensed Products in the Territory) in excess of the Development Cost Cap for the Licensed Products equally (50:50), exclusive of any JGS Territory Extra Costs (as defined below) incurred by BeiGene, which shall be reimbursed by AssemblyBio in accordance with Section 5.4(c). For clarity, except as provided under Section 5.5(c), BeiGene shall not share in any costs and expenses of AssemblyBio outside of the Territory pursuant to this Section 5.4.

(c) **JGS Territory Extra Costs**. If the actual portion of patients enrolled in the Territory by BeiGene for a Joint Global Study exceeds [* * *] of all patients enrolled worldwide, AssemblyBio shall reimburse the Development and Regulatory Costs incurred by BeiGene that are directly attributed or fairly allocable to the enrollment of the number of patients over [* * *] of all patients enrolled worldwide (the "**JGS Territory Extra Patients**") and the portion of Clinical Trials conducted in the Territory with respect to such JGS Territory Extra Patients that constitute part of the Joint Global Study (the "**JGS Territory Extra Costs**"). If AssemblyBio is obligated to reimburse any JGS Territory Extra Costs under this Section 5.4(c) during any Calendar Quarter, BeiGene shall issue an invoice for such JGS Territory Extra Costs incurred during such Calendar

Quarter that are subject to such reimbursement within [* * *] after the end of such Calendar Quarter, and AssemblyBio shall pay the undisputed invoiced amounts within [* * *] after the receipt of such invoice. On an annual basis or as may be otherwise agreed between the Parties, the Parties will coordinate through the JDC regarding any overpayments or underpayments made by AssemblyBio during the immediately preceding Calendar Year and an adjustment payment shall be made by or to AssemblyBio so that the total reimbursement amount paid by AssemblyBio for such Calendar Year equals the actual JGS Territory Extra Costs incurred by BeiGene during such Calendar Year.

(d) **Territory Only Case Budget**. For each of the (i) Licensed ABI-H0731 Product, (ii) Licensed ABI-H2158 Product, and (iii) Licensed ABI-H3733 Product, the Parties will discuss through the JDC and agree upon a baseline budget for the Territory Only Case for such Licensed ABI-H0731 Product, Licensed ABI-H2158 Product or Licensed ABI-H3733 Product (as applicable), setting forth the total expenditure of Development and Regulatory Costs that would be incurred therefor in the scenario of a Territory Only Case (the "**Territory Only Case Budget**"). In the event that the Parties disagree regarding the Territory Only Case Budget, [* * *]. The budget for BeiGene's Development activities in the Territory under the applicable Development Plan shall be consistent with the Territory Only Case Budget. Notwithstanding any provisions to the contrary hereunder, in the event BeiGene's total expenditure on Development and Regulatory Costs in the Territory for a Joint Global Study for the initial Regulatory Approval in relation to a Licensed ABI-H0731 Product, Licensed ABI-H2158 Product or Licensed ABI-H3733 Product (as applicable) exceeds the applicable Territory Only Case Budget, [* * *].

(e) **Cost Sharing Examples**. For the avoidance of doubt, the cost-sharing concepts set forth under this Section 5.4 are intended to follow the principles and examples set forth in Exhibit 5.4(e).

(f) **Development and Regulatory Costs**. For clarity, all Development and Regulatory Costs covered under this Section 5.4 will be subject to the restrictions set forth in the definition of "Development and Regulatory Costs", including clauses (x), (y) and (z) and the treatment of budget overage thereunder.

5.5 New Development Activities in the Territory.

(a) **New Development Proposal**. Either Party may propose with respect to the Licensed Products in the Territory new Development activities (including the Development of a Licensed Product for a new Indication or as part of a Combination Product, excluding the Development of Licensed Products before the Initiation of Phase 3 Clinical Trial thereof) not currently set forth in an existing Territory Development Plan with its study design, protocol, specific Development activities allocated to each Party, and the budget for such allocated activities (each proposal, a "**New Development Proposal**"). The JDC will review, discuss and determine whether to approve each New Development Proposal within [* * *] after the receipt thereof. If the JDC approves by consensus such New Development Proposal, (i) the Parties will, through the JDC, update the Territory Development Plan to include the Development activities proposed in the New Development Proposal, and (ii) the Development and Regulatory Costs incurred with respect to the Development activities proposed in the approved New Development Proposal will be subject to Section 5.4.

(b) **Unilateral Development Activities**. If the JDC does not approve a New Development Proposal, then the proposing Party may not exercise its final decision-making authority under Section 3.2(f) to override such JDC decision, but may proceed with such proposed Development activities in the Territory at its own cost and expense (such activities, the "**Unilateral Development Activities**"); *except* that if the non-proposing Party objects to such New Development Proposal based on the AssemblyBio Veto Right or BeiGene Veto Right (as applicable), the proposing Party shall not proceed with such proposed Development activities in such New Development Proposal. The other Party shall not have access to the Know-How and Clinical Data generated through the Unilateral Development Activities, unless and until such other Party reimburses the proposing Party [* * *] of the Costs incurred by the proposing Party in relation to the conduct of the Unilateral Development Activities. Notwithstanding the foregoing, the other Party may access safety data resulting from such Unilateral Development Activities pursuant to Section 5.9 without the foregoing payment obligation.

(c) **AssemblyBio Ancillary Trials**. The Parties acknowledge that AssemblyBio will conduct certain AssemblyBio Ancillary Trials which may be outside of the scope of any Development Plan. AssemblyBio will be solely responsible for conducting such AssemblyBio Ancillary Trials outside of the Development Plans at its own costs. The proposed budget for the AssemblyBio Ancillary Trials for the Licensed ABI-H0731 Products in the pipeline as of the Effective Date is set forth on Exhibit 5.5(c) (the "**AssemblyBio Ancillary Trials Budget**"). In the event BeiGene elects to have access and a right of reference to the Know-How and the Clinical Data resulting from any such AssemblyBio Ancillary Trial(s) (other than safety data which will be exchanged in accordance with Section 5.9), BeiGene shall reimburse AssemblyBio [* * *] of the Costs incurred by AssemblyBio in relation to such AssemblyBio Ancillary Trial(s) (only to the extent such Costs are incurred after the Effective Date), *provided* that (i) with respect to AssemblyBio Ancillary Trials for the Licensed ABI-H0731 Products, such reimbursement obligations shall not apply to any such Costs [* * *]; and (ii) with respect to AssemblyBio Ancillary Trials for the Licensed ABI-H2158 Products or for Licensed ABI-H3733 Products, BeiGene's reimbursement obligations under this Section 5.5(c) shall only apply to the extent [* * *] and the Costs incurred by AssemblyBio in relation to such AssemblyBio Ancillary Trials for Licensed ABI-H2158 Products or for Licensed ABI-H3733 Products (as applicable) do not [* * *] (i) (adjusted to [* * *]). All such Costs must be recorded in accordance with the Accounting Standards and either directly attributed to or fairly allocable to the conduct of the AssemblyBio Ancillary Trials.

5.6 Development Records. BeiGene shall maintain reasonably complete, current and accurate records of (a) all Development activities conducted by or on behalf of BeiGene, its Affiliates or its sublicensees pursuant to this Agreement, the Global Development Plan or the Territory Development Plan, (b) all Development and Regulatory Costs incurred in connection with such Development activities, and (c) all data and other information resulting from such activities, in each case in accordance with all Applicable Laws. BeiGene shall maintain such records during the Term and for a period of time after the Term consistent with Applicable Laws and reasonable industry practices on record retention and destruction (which shall not be less than three (3) years). Such records will be in English (or include complete English translations) and shall fully and properly reflect all work done and results achieved by or on behalf of BeiGene in the performance of the Development activities in the Territory hereunder, in good scientific manner appropriate for regulatory and patent purposes. BeiGene shall document all non-clinical

studies and Clinical Trials of a Licensed Product in formal written study reports in accordance with Applicable Laws and national and international guidelines (*e.g.*, GCP, GLP and cGMP). Upon AssemblyBio's request, BeiGene shall, and shall cause its Affiliates and sublicensees to, provide AssemblyBio with copies of such records.

5.7 Clinical Trial Audit Rights.

(a) Upon reasonable notification by AssemblyBio and at AssemblyBio's cost and expense, AssemblyBio or its representatives shall be entitled to conduct an audit of any Clinical Trial sites or vendors engaged, or other facilities used, by BeiGene or its Affiliates or sublicensees to conduct BeiGene's obligations under the Global Development Plan and Territory Development Plan, to ensure that such Clinical Trials are conducted in compliance with the Global Development Plan, Territory Development Plan and all Applicable Laws, including GCP. No later than [* * *] following the completion of any such audit, AssemblyBio will provide BeiGene with a written summary of AssemblyBio's findings in English, including any deficiencies or other areas of remediation that AssemblyBio reasonably identifies during such audit and the Parties shall promptly meet to discuss any such deficiencies or other areas of remediation identified by AssemblyBio. BeiGene will use Commercially Reasonable Efforts to remediate such deficiencies promptly following BeiGene's receipt of such report, at BeiGene's cost and expense.

(b) BeiGene will provide AssemblyBio with copies of all quality oversight or audit reports, including certified translations into English thereof, prepared in connection with any audit that BeiGene, its Affiliates or sublicensees conduct of a Clinical Trial site or vendor that BeiGene, its Affiliates or sublicensees have engaged or are evaluating to potentially engage to fulfill BeiGene's obligations under the Global Development Plan or the Territory Development Plan no later than [* * *] after receiving or preparing, as applicable, any such report.

5.8 Development Reports. BeiGene shall provide AssemblyBio with [* * *] written reports (which may be in the form of PowerPoint or Excel presentations), at least [* * *], summarizing its, its Affiliates' and its sublicensees' Development of Licensed Products, including a summary of the results of such Development and the Development and Regulatory Costs incurred in connection with such Development activities, which reports shall be in English (the "**BeiGene Development Report**"). Without limiting the foregoing, such reports shall contain (a) sufficient detail to enable AssemblyBio to assess BeiGene's compliance with its Development obligations hereunder, (b) the total amount of and a detailed summary of Development and Regulatory Costs incurred for the Development activities conducted by BeiGene for each Licensed Product in each region during the past [* * *], including, as may be applicable, the Development and Regulatory Costs incurred for any Joint Global Study, (c) the cumulative amount of Development and Regulatory Costs that have been incurred by BeiGene to date from the Effective Date subject to Section 5.4, and (d) a non-binding good-faith estimate of the Development and Regulatory Costs to be incurred by BeiGene during the then-ongoing [* * *]. Without limiting the foregoing, within [* * *] following the end of each [* * *], BeiGene shall provide AssemblyBio with a good-faith estimate of information under foregoing clauses (b) through (d) to be set forth in the next BeiGene Development Report to follow. Subject to AssemblyBio's right to use and disclose data and results in accordance with Section 5.9 and the licenses and rights granted to AssemblyBio in Section 2.4, such reports shall be Confidential Information of BeiGene pursuant to Article 10. BeiGene shall promptly respond to AssemblyBio's reasonable requests from time to time for additional information regarding material Development activities. The Parties shall review

each BeiGene Development Report and discuss the status, progress and results of Development activities and the related costs at JSC meetings, and AssemblyBio shall keep BeiGene reasonably informed through the JDC as to any material developments with respect to the Development of Licensed Products outside the Territory.

5.9 Data Exchange and Use. In addition to its adverse event and safety data reporting obligations pursuant to Section 6.4 and *except* to the extent excluded pursuant to Sections 5.5(b) and 5.5(c), each Party shall promptly (but in any event no later than [* * *] from the other Party's request) provide the other Party with copies of all data and results, including all Clinical Data and all supporting documentation (*e.g.*, protocols, CRFs, analysis plans) Controlled by such Party or its Affiliates that are generated by or on behalf of such Party or its Affiliates or sublicensees, if applicable, in the Development of Licensed Products; *provided* that AssemblyBio shall only be required to provide BeiGene such data, results and documentation to the extent it comprises AssemblyBio Know-How and is necessary or reasonably useful for BeiGene's Development or Commercialization of the Licensed Products in the Field in the Territory, including any such data, results and documentation that are reasonably requested by BeiGene or that are necessary to support filings for Regulatory Approval for a Licensed Product in the Territory. AssemblyBio agrees to use Commercially Reasonable Efforts to [* * *]. BeiGene shall have the right to use and reference such data and results provided by AssemblyBio, without additional consideration, for the purpose of obtaining and maintaining Regulatory Approvals and any Pricing and Reimbursement Approvals, as applicable, of Licensed Products in the Field in the Territory. AssemblyBio and its designees shall have the right to use and reference such data and results provided by BeiGene, without additional consideration, for the purpose of (a) Developing, Manufacturing and Commercializing Licensed Products in accordance with the licenses granted under Section 2.4, (b) filing Patent Rights covering AssemblyBio's Inventions and Product-Specific IP, (c) obtaining and maintaining Regulatory Approval and any Pricing and Reimbursement Approvals, as applicable, of Licensed Products outside the Field in the Territory or outside of the Territory, and (d) seeking, obtaining and maintaining a Clinical Trials Application for any Licensed Product in the Field in the Territory in accordance with AssemblyBio's retained rights under Section 2.3. For clarity, any such data or results that are Inventions will be owned in accordance with Section 14.1 and subject to the licenses, rights and obligations set forth herein.

5.10 Subcontractors.

(a) BeiGene shall have the right to engage subcontractors for purposes of conducting activities assigned to it under this Agreement or for which it is responsible under this Agreement. BeiGene shall cause any subcontractor engaged by it to be bound by written obligations of confidentiality and non-use consistent with this Agreement prior to performing any activities. BeiGene shall cause its subcontractors to assign to BeiGene (or, in the case of academic institutions or Clinical Trial sites, use reasonable efforts to cause such subcontractor to so assign, and in any event cause such entity to grant an option for a license to use) all intellectual property made by such subcontractor in the course of performing such subcontracted work. BeiGene shall remain directly responsible for any obligations under this Agreement that have been delegated or subcontracted to any subcontractor and shall be directly responsible for the performance of its subcontractors.

(b) Without limiting the foregoing, BeiGene shall obtain AssemblyBio's written approval, such approval not to be unreasonably withheld, conditioned or delayed, prior to engaging any contract research organization to perform services (i) [* * *], or (ii) [* * *].

(c) AssemblyBio may conduct any activities assigned to it under the Global Development Plan or this Agreement through one or more Affiliates or Third Party designees.

ARTICLE 6
REGULATORY

6.1 Holder of Regulatory Approvals and Regulatory Submissions. To the extent permissible under Applicable Law, BeiGene shall be the holder of Regulatory Approvals and Regulatory Submissions for Licensed Products in the Field in the Territory. To the extent the foregoing is not permissible under Applicable Law, then AssemblyBio shall be the holder of Regulatory Approvals and Regulatory Submissions for Licensed Products in the Field in the Territory, and BeiGene shall act as the authorized regulatory agent of record for AssemblyBio in the Territory and take actions on behalf of and for the benefit of AssemblyBio in accordance with the Applicable Law. AssemblyBio shall reasonably cooperate with BeiGene, at BeiGene's request and expense, to enable BeiGene to obtain any or all such Regulatory Approvals and Regulatory Submissions.

6.2 Review of Regulatory Submissions.

(a) BeiGene shall provide to AssemblyBio all Regulatory Submissions (including certified English translations thereof) prepared by or on behalf of BeiGene at least [* * *] prior to submission and shall consider in good faith any reasonable comments received from AssemblyBio with respect thereto. AssemblyBio shall provide BeiGene with copies of all Clinical Trial Applications for the Licensed ABI-H0731 Products in the Territory (including certified English translations thereof) prepared by or on behalf of AssemblyBio.

(b) In addition, each Party shall notify the other Party of any comments or other material correspondence regarding any Regulatory Submissions that are received from any Regulatory Authority in the Territory or, with respect to Clinical Trials conducted pursuant to the Global Development Plan, outside the Territory, and shall provide the other Party with copies thereof as soon as reasonably practicable, but in all events within [* * *] of receipt (or such longer time period as may be necessary to obtain translations thereof). Each Party will provide quarterly updates, at each JDC meeting, regarding its activities and progress with respect to all Clinical Trials conducted pursuant to the Global Development Plan or the Territory Development Plan.

(c) Each Party shall keep the other Party reasonably informed of regulatory developments related to Licensed Products in the Field in the Territory and outside the Territory of which it becomes aware and shall promptly notify the other Party in writing of any material decision by any Regulatory Authority in the Field, in the Territory and outside the Territory, of which it becomes aware regarding any Licensed Product.

(d) Each Party shall provide the other Party with notice no later than [* * *] after receiving notice of any material meeting or substantive communication with any Regulatory Authority in the Territory related to any Licensed Product in the Field. Each Party shall provide

the other Party with a written summary of each such meeting or substantive communication in English promptly following such meeting or discussion. AssemblyBio or its designee will have the right, but not the obligation, to attend and observe any such meeting or discussion with Regulatory Authorities in the Territory unless prohibited or restricted by Applicable Law or the Regulatory Authorities; *provided* that BeiGene shall not be obligated to schedule such meetings to specifically enable AssemblyBio's or its designee's attendance. Without limiting the generality of the foregoing, with respect to ABI-H0731 and Licensed ABI-H0731 Products, (i) until the study protocols of the Phase 3 Clinical Trials for the Licensed ABI-H0731 Products are approved by the applicable Regulatory Authorities in the Territory, AssemblyBio shall be the leading Party for the discussion and interactions with Regulatory Authorities in the Territory with respect to the Licensed ABI-H0731 Products, taking into account in good faith comments and input from BeiGene related thereto; (ii) after the study protocols of the Phase 3 Clinical Trials for the Licensed ABI-H0731 Products are approved by the applicable Regulatory Authorities in the Territory, BeiGene shall be the leading Party for the discussion and interactions with Regulatory Authorities in the Territory with respect to the Licensed ABI-H0731 Products, taking into account in good faith comments and input from AssemblyBio related thereto; and (iii) BeiGene shall have the right to participate in any meeting between AssemblyBio and Regulatory Authorities in the Territory regarding the Clinical Trials for ABI-H0731 and Licensed ABI-H0731 Products unless prohibited or restricted by Applicable Law or the Regulatory Authorities, *provided* that AssemblyBio shall not be obligated to schedule such meetings to specifically enable BeiGene's or its designee's attendance.

6.3 Right of Reference. Each Party hereby grants to the other Party the right of reference to all Regulatory Submissions pertaining to Licensed Products in the Field submitted by or on behalf of such Party or its Affiliates, solely to the extent reasonably necessary for the purposes set forth in this Section 6.3 and requested by such other Party. BeiGene may use such right of reference to AssemblyBio's Regulatory Submissions solely for the purpose of seeking, obtaining and maintaining Regulatory Approvals and any Pricing and Reimbursement Approvals, as applicable, of Licensed Products in the Field in the Territory. AssemblyBio may use such right of reference to BeiGene's Regulatory Submissions and Regulatory Approvals solely for the purpose of (a) seeking, obtaining and maintaining Regulatory Approvals and any Pricing and Reimbursement Approval of Licensed Products outside the Territory or (b) seeking, obtaining and maintaining a Clinical Trials Application for any Licensed Product in the Field in the Territory only to the extent included within AssemblyBio's retained rights under Section 2.3. The Party requesting such right of reference shall bear the reasonable costs and expenses of the other Party associated with providing the right of reference pursuant to this Section 6.3. Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 6.3 and to give the other Party the benefit of the rights of reference to the granting Party's Regulatory Submissions in the other Party's territory as provided herein.

6.4 Adverse Events Reporting. Within [* * *] after the Effective Date, BeiGene and AssemblyBio shall develop and agree in a written agreement to worldwide safety and pharmacovigilance procedures for the Parties with respect to Licensed Products, such as safety data sharing and exchange, adverse events reporting and prescription events monitoring (the "**Pharmacovigilance Agreement**").

6.5 Safety and Regulatory Audits and Inspections.

(a) **Safety and Regulatory Audits**. Upon reasonable advance (not less than [* * *] written notification), AssemblyBio or its representatives shall be entitled to conduct an audit of the safety and regulatory systems, procedures or practices of BeiGene and its Affiliates relating to the Licensed Products no more often than [* * *] period. Upon AssemblyBio's reasonable request, BeiGene will conduct such audits of its sublicensees and subcontractors hereunder (subject to the terms and conditions of BeiGene's agreements with such sublicensees and subcontractors) and provide AssemblyBio with the results of such audits.

(b) **Safety and Regulatory Inspections**. BeiGene shall promptly notify AssemblyBio of any inspection of BeiGene, its Affiliates, CMOs, sublicenses or subcontractors (including Clinical Trial sites) by any Regulatory Authority relating to Licensed Products and shall provide AssemblyBio with all information in BeiGene's Control pertinent thereto. Without limiting the foregoing, BeiGene shall permit Regulatory Authorities outside the Territory to conduct inspections of BeiGene, its Affiliates, CMOs, sublicensees or subcontractors (including Clinical Trial sites) relating to Licensed Products, and shall ensure that such Affiliates, CMOs, sublicensees and subcontractors permit such inspections. AssemblyBio shall have the right, but not the obligation, to be present at and participate in any such inspection described in this Section 6.5(b) [* * *]. BeiGene will provide AssemblyBio with a written summary in English of any findings of a Regulatory Authority relating to Licensed Products following a regulatory audit (and any written correspondences in relation thereto) within [* * *] following any such audit, and will provide AssemblyBio with an unredacted copy of any report issued by such Regulatory Authority, including if applicable, a certified English translation thereof within [* * *] following such audit.

6.6 No Harmful Actions. If either Party reasonably believes that the other Party is taking or intends to take any action with respect to a Licensed Product in such other Party's territory that would reasonably be expected to have a material adverse impact upon the regulatory status of any Licensed Product in the Field in its respective territory, then such Party shall have the right to bring the matter to the attention of the JSC, and the Parties shall discuss in good faith a resolution to such concern. Without limiting the foregoing, unless the Parties otherwise agree (or unless otherwise set forth herein or in the Global Development Plan): (a) neither Party shall communicate with any Regulatory Authority having jurisdiction outside of its respective territory with respect to any Licensed Product, unless required by such Regulatory Authority, in which case such Party shall notify the other Party of such order within [* * *] of such communication; and (b) neither Party shall submit any Regulatory Submissions or seek Regulatory Approvals for any Licensed Product in the other Party's respective territory, *except* AssemblyBio's right to seek, obtain and maintain Clinical Trial Applications for the Licensed Products in the Field in the Territory in accordance with AssemblyBio's retained rights under Section 2.3, which shall not be limited.

6.7 Notice of Regulatory Action. If any Regulatory Authority takes or gives notice of its intent to take any regulatory action with respect to any activity of BeiGene relating to the Licensed Product, then BeiGene shall notify AssemblyBio of such notice within [* * *] of its receipt thereof. AssemblyBio shall have the right to review and comment on any responses to Regulatory Authorities that pertain to a Licensed Product promptly and in any event within [* * *] of receipt of such proposed response. BeiGene will [* * *] to a Licensed Product in the Territory and will [* * *]. AssemblyBio will [* * *] to a Licensed Product outside of the Territory and will

[* * *]. The costs and expenses of any regulatory action in the Territory will be included among the Development and Regulatory Costs and shared in accordance with Section 5.4. In addition, each Party shall promptly notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from a Third Party that, in the case of notice to AssemblyBio, would reasonably be expected to materially affect the Development or Commercialization of the Licensed Products, and in the case of notice to BeiGene, would reasonably be expected to materially affect the Development or Commercialization of the Licensed Products in the Field in the Territory.

ARTICLE 7.
MANUFACTURING

7.1 Manufacture of Licensed Product for the Territory. Subject to the terms and conditions of this Article 7, BeiGene shall have the right to (a) purchase Development supply from AssemblyBio or AssemblyBio's CMO pursuant to the Clinical Supply Agreement, and (b) purchase commercial supply of Licensed Product from AssemblyBio or AssemblyBio's CMO pursuant to the Commercial Supply Agreement.

7.2 Supply by AssemblyBio.

(a) **Development Supply**. AssemblyBio shall, either by itself or through a CMO, Manufacture and supply to BeiGene all Licensed Products required by BeiGene for Development use in the Territory under the Territory Development Plan and for BeiGene's Development-related responsibilities under the Global Development Plan, subject to the terms and conditions of the Clinical Supply Agreement. The Parties shall use Commercially Reasonable Efforts to enter into an agreement governing the supply by AssemblyBio of such Licensed Products for such Development use by BeiGene ("**Clinical Supply Agreement**") within [* * *] after the Effective Date, pursuant to which BeiGene shall purchase its clinical requirements for Licensed Product in the Territory from AssemblyBio. AssemblyBio shall supply the Licensed Products pursuant to this Section 7.2(a) in [* * *] at a transfer price [* * *]. AssemblyBio shall invoice BeiGene for Licensed Products [* * *] in accordance with this Section 7.2 and BeiGene shall, subject to the terms of the Clinical Supply Agreement, pay the undisputed invoiced amounts within [* * *] after the date of such invoice. Notwithstanding the foregoing, in the event AssemblyBio will incur, [* * *], any advance fee or charge, including a slot reservation fee, advance raw material charges, or other similar fees or charges for Manufacture of Licensed Product solely for BeiGene, AssemblyBio may invoice BeiGene for such fee or charge, as applicable, [* * *], and BeiGene shall, pay such invoiced amounts within [* * *] after the date of such invoice. Amounts paid by BeiGene for clinical supply of Licensed Products under this Agreement will be included among Development and Regulatory Costs and shared by the Parties in accordance with Section 5.4.

(b) **Commercial Supply**. The Parties shall use Commercially Reasonable Efforts to agree, not later than [* * *] prior to the anticipated launch date of a Licensed Product in the Territory, on the principal terms of a commercial supply agreement (the "**Commercial Supply Agreement**") pursuant to which BeiGene shall purchase commercial supply of a Licensed Product for the Territory from AssemblyBio or AssemblyBio's CMO. The transfer price under the Commercial Supply Agreement shall be [* * *]. The terms of the Commercial Supply Agreement shall be consistent with the terms and conditions of this Agreement, the applicable terms and

conditions of Clinical Supply Agreement, and the terms and conditions of any agreement between AssemblyBio and its CMOs, to the extent applicable to commercial supply of Licensed Product in the Field in the Territory. The Parties shall negotiate in good faith and endeavor to enter into such Commercial Supply Agreement at least [* * *] prior to the estimated date of enrollment of the last patient in the first Phase 3 Clinical Trial of such Licensed Product in the Territory. Unless and until otherwise agreed by the Parties, and *except* as otherwise set forth in the Commercial Supply Agreement, BeiGene shall purchase its commercial requirements for Licensed Product in the Territory from AssemblyBio pursuant to the Commercial Supply Agreement. AssemblyBio shall invoice BeiGene for the Licensed Products [* * *] and BeiGene shall, subject to the terms of the Commercial Supply Agreement, pay the undisputed invoiced amounts within [* * *] after the date of such invoice.

(c) **Delivery**. Delivery of Licensed Products supplied by AssemblyBio for Development and Commercialization will be made EXW (Incoterms 2020) designated facilities of AssemblyBio or its CMOs. BeiGene shall contract for shipment and insurance of such Licensed Product from AssemblyBio's or its CMO's facility. BeiGene shall be responsible for obtaining all licenses or other authorizations for the importation of such Licensed Product, [* * *]. BeiGene shall also be responsible for the clinical packaging, labeling, QC/QA/QP release, storage, customs clearance and distribution of such Licensed Product, [* * *].

(d) **Fully Burdened Manufacturing Cost Adjustment**.

(i) BeiGene and AssemblyBio will act in good faith and use Commercially Reasonable Efforts to work with each other to reduce the Fully Burdened Manufacturing Cost under both the Clinical Supply Agreement and Commercial Supply Agreement. Fully Burdened Manufacturing Cost reduction measures, along with all discussions and decisions regarding Manufacturing will be discussed and decided through the JMC. The Fully Burdened Manufacturing Cost reduction measures to be discussed at the JMC may include: (A) activities and measures required to streamline, enhance and optimize the manufacturing process, including for materials and equipment related thereto, (B) the possibility of BeiGene taking on some, or all, of Manufacturing for the Territory and/or potentially becoming a second supplier for AssemblyBio globally, and (C) any other technical or business solutions aimed at reducing Fully Burdened Manufacturing Cost (collectively, "**Joint COGM Improvements**").

(ii) If the [* * *] Fully Burdened Manufacturing Cost with respect to any Calendar Quarter is greater than [* * *], then upon written notice by BeiGene to AssemblyBio, the Parties agree to promptly discuss in good faith appropriate adjustment or compensation to be provided by AssemblyBio to BeiGene (including [* * *]), taking into account: (A) [* * *], (B) [* * *], (C) [* * *], and (D) [* * *]. If the Parties cannot agree, such decision will be referred to the Executive Officers for decision in accordance with Section 16.6(a) and, if the Executive Officers cannot agree, [* * *].

(iii) For clarity, if the Fully Burdened Manufacturing Cost with respect to any Calendar Quarter is equal to or below [* * *], then Section 7.2(d)(ii) shall not apply with respect to such Calendar Quarter, and instead Section 9.6(c)(v) shall apply, if and as applicable, with respect to such Calendar Quarter. Notwithstanding any provision to the contrary hereunder, in no event shall both Sections 7.2(d)(ii) and 9.6(c)(v) apply at the same time.

(e) **Single Agreement**. The Parties may agree to execute a single supply agreement pursuant to which AssemblyBio (or its CMO) would supply BeiGene Licensed Products for the Territory, rather than a separate Clinical Supply Agreement and Commercial Supply Agreement.

7.3 Manufacturing in Territory. In the event that (a) the Applicable Laws or the Regulatory Authorities in the Territory require, or (b) BeiGene becomes aware of any potential changes under the Applicable Laws or the requirements of Regulatory Authorities in the Territory that are reasonably likely to become effective within the next [* * *], which would require, in either case (a) or (b), the Licensed Products to be Manufactured in the Territory, then BeiGene shall bring this matter to the attention of JMC to be discussed in good faith between the Parties. If the Parties agree, or if in the opinion of BeiGene's external legal counsel, such requirement under the Applicable Laws or by Regulatory Authorities exist or are likely to become effective in the Territory within the next [* * *], then the Parties shall discuss and approve appropriate measures to meet such actual or potential requirements, which may include: (i) AssemblyBio to Manufacture, or have Manufactured through its CMO, the applicable Licensed Products in the Territory for supply to BeiGene, or (ii) BeiGene to take on some or all of the Manufacturing activities of the applicable Licensed Products in the Territory.

ARTICLE 8
COMMERCIALIZATION

8.1 Commercialization Responsibility.

(a) BeiGene shall be solely responsible for Commercializing the Licensed Products in the Field in the Territory in accordance with this Article 8 and shall book all sales of such Licensed Products in the Territory. BeiGene shall use Commercially Reasonable Efforts to Commercialize each Licensed Product in each region in which such Licensed Product receives Regulatory Approval and Pricing and Reimbursement Approval in the Field. BeiGene shall conduct all Commercialization of Licensed Products in the Field in the Territory in accordance with the Global Commercialization Principles (subject to [* * *]) and the Territory Commercialization Plan for such Licensed Product and all Applicable Laws, at its sole cost and expense.

(b) As between the Parties, AssemblyBio shall have the sole right to Commercialize each Licensed Product outside of the Territory and outside the Field in the Territory, and to book all such sales of Licensed Products outside of the Territory and outside the Field in the Territory.

8.2 Global Commercialization Principles and Territory Commercialization Plan.

(a) **Global Commercialization Principles**. AssemblyBio shall prepare and deliver an initial draft of the Global Commercialization Principles to the JCC for its review, discussion and approval not later than [* * *] prior to the anticipated date of the first filing of the first Regulatory Approval for the applicable Licensed Product in any country or jurisdiction. Thereafter, either Party may propose updates or amendments to the Global Commercialization Principles, which updates or amendments shall be reviewed and approved by the JCC.

(b) **Territory Commercialization Plan**. The Territory Commercialization Plan with respect to a Licensed Product shall contain in reasonable detail the major Commercialization activities planned for such Licensed Product in the Territory, including any activities in relation to medical affairs. The Territory Commercialization Plan shall be consistent with the Global Commercialization Principles. BeiGene shall deliver an initial draft of the Territory Commercialization Plan to the JCC for its review, discussion and approval no later than [* * *] prior to the anticipated date of the first filing of the first Regulatory Approval for a Licensed Product in the Territory. AssemblyBio shall have the right to comment through the JCC on such Territory Commercialization Plan, and BeiGene shall [* * *] prior to finalizing such Territory Commercialization Plan. BeiGene shall promptly provide AssemblyBio with a copy of such final Territory Commercialization Plan, and thereafter, from time to time, but at least [* * *], BeiGene shall propose updates or amendments to the Territory Commercialization Plan to reflect any changes in such plans, including those made in response to changes in the marketplace, relative commercial success of such Licensed Product, and other relevant factors that may influence such plan and activities. BeiGene shall submit the proposed updated or amended Territory Commercialization Plan to the JCC for review, discussion and approval before implementing such update or amendment.

8.3 Commercialization Reports. For each Calendar Year following receipt of the first Regulatory Approval and, if applicable, Pricing and Reimbursement Approval for any Licensed Product in any region in the Territory, BeiGene shall provide to AssemblyBio annually within [* * *] after the end of each Calendar Year a written report that summarizes the Commercialization activities on a Licensed Product-by-Licensed Product and region-by-region basis, as applicable, performed by or on behalf of BeiGene, its Affiliates and sublicensees in the Territory since the prior report provided by BeiGene. Such reports shall be Confidential Information of BeiGene, subject to Article 10. BeiGene shall provide updates to any such report at each meeting of the JSC and the JCC.

8.4 Coordination of Commercialization Activities.

(a) The Parties recognize that they may benefit from the coordination of certain activities in support of the Commercialization of Licensed Products in and outside the Territory. As such, the Parties shall coordinate such activities where appropriate, which may include scientific and medical communication and product positioning.

(b) BeiGene shall keep AssemblyBio timely informed on the status of any application for Pricing and Reimbursement Approvals for Licensed Products in the Field in the Territory, including any discussion with the applicable Regulatory Authority with respect thereto. Each Party shall have the right to determine the price of Licensed Products sold in its territory and neither Party shall have the right to direct, control or approve the pricing of Licensed Products sold by the other Party in such other Party's territory, *provided* that all pricing matters for Licensed Products in the Territory shall be reviewed and discussed by the JCC, subject to BeiGene's final decision-making authority on such pricing matters.

(c) BeiGene will use Commercially Reasonable Efforts to cooperate with AssemblyBio in AssemblyBio's development and adoption of a global branding strategy for the Licensed Products, which may include certain distinctive colors, logos, images, symbols, and trademarks to be used in connection with the Commercialization of Licensed Products on a global

basis (such branding elements, collectively, the "**Global Brand Elements**"). AssemblyBio shall own all rights in such Global Brand Elements and shall grant BeiGene the exclusive right to use such Global Brand Elements in connection with the Commercialization of Licensed Products in the Field in the Territory. BeiGene shall Commercialize Licensed Products in the Territory in a manner consistent with the Global Brand Elements to the extent included in the Territory Commercialization Plan. The branding strategy in the Territory shall be included in the Territory Commercialization Plan and reviewed by the JCC, subject to BeiGene's final decision-making authority on such branding matters.

8.5 Diversion. Each Party covenants and agrees that it shall not, and shall ensure that its Affiliates and sublicensees shall not, either directly or indirectly, promote, market, distribute, import, sell or have sold any Licensed Products, including via the Internet or mail order, to any Third Party or to any address or Internet Protocol address or the like in the other Party's territory; *provided* that each Party shall have the right to attend conferences and meetings of congresses in the other Party's territory and to promote and market Licensed Products to Third Party attendees at such conferences and meetings, subject to this Section 8.5. Neither Party shall engage, nor permit its Affiliates or sublicensees to engage, in any advertising or promotional activities relating to any Licensed Products for use directed primarily to customers or other buyers or users of Licensed Products located in any country or jurisdiction in the other Party's territory, or solicit orders from any prospective purchaser located in any country or jurisdiction in the other Party's territory. If a Party or its Affiliate or sublicensee receives any order for Licensed Products for use from a prospective purchaser located in a country or jurisdiction in the other Party's territory, such Party shall immediately refer that order to such other Party and shall not accept any such orders. Neither Party shall, nor permit its Affiliates, sublicensees or distributors to, deliver or tender (or cause to be delivered or tendered) any Licensed Products for use in the other Party's territory.

ARTICLE 9
PAYMENTS

9.1 Upfront Fee. In partial consideration of AssemblyBio's granting of the licenses and rights to BeiGene hereunder and AssemblyBio's undertaking of the activities required under this Agreement, BeiGene shall pay to AssemblyBio a one-time, non-refundable, non-creditable upfront payment of forty million USD ($40,000,000) (the "**Upfront Payment**") within [* * *] following the Effective Date.

9.2 Development Milestones. Within [* * *] after the achievement of each milestone event set forth in the table below for each of the [* * *] Licensed Products (each, a "**Development Milestone Event**"), BeiGene shall make the corresponding milestone payment to AssemblyBio (each, a "**Development Milestone Payment**") in accordance with Section 9.5(a). Subject to Section 9.4, each Development Milestone Payment shall be payable [* * *] Licensed Products, upon the [* * *] of the corresponding Development Milestone Event for such Licensed Product.

Development Milestone Event	**Milestone Payment**		
	[* * *]	[* * *]	[* * *]
	[* * *]		
1. [* * *]*	[* * *]	[* * *]	[* * *]
2. [* * *]*	[* * *]	[* * *]	[* * *]
3. [* * *]**, ***	[* * *]	[* * *]	[* * *]
4. [* * *]	[* * *]	[* * *]	[* * *]
5. [* * *]	[* * *]	[* * *]	[* * *]

* Only [* * *] will be due for the [* * *] of a Licensed Product [* * *].
** If any Licensed Product achieves [* * *] without [* * *] (as such [* * *] may be applicable to such Licensed Product), then [* * *] will become payable [* * *].
*** As an example, in the event [* * *], it will [* * *] and AssemblyBio will receive [* * *]. If subsequently [* * *], then [* * *] will [* * *] ([* * *]) and [* * *] ([* * *]).

The Development Milestone Payments set forth above are payable [* * *] Development Milestone Event for [* * *]. For the purpose of this Agreement, "[* * *]" means [* * *].

9.3 Commercialization Milestones. Upon the [* * *] achievement of each milestone event set forth in the table below with respect to a particular Licensed Product (each, a "**Commercialization Milestone Event**") for [* * *] Licensed Products, BeiGene shall make the corresponding milestone payment to AssemblyBio (each, a "**Commercialization Milestone Payment**") in accordance with Section 9.5(b):

Commercialization Milestone Event*	**Milestone Payment**		
	[* * *]	[* * *]	[* * *]
	[* * *]		
1. [* * *]	[* * *]	[* * *]	[* * *]
2. [* * *]	[* * *]	[* * *]	[* * *]
3. [* * *]	[* * *]	[* * *]	[* * *]
4. [* * *]	[* * *]	[* * *]	[* * *]

* As an example, in the event [* * *], it will [* * *] and AssemblyBio will receive [* * *]. If thereafter, [* * *], then it will [* * *], and AssemblyBio will receive [* * *].

The Commercialization Milestone Payments set forth above are payable [* * *].

In the event that [* * *], BeiGene shall pay AssemblyBio [* * *]. For example, if [* * *], BeiGene would pay AssemblyBio [* * *] in Commercialization Milestone Payments pursuant to this Section 9.3. Each milestone payment set forth above shall be payable [* * *] Licensed Product.

9.4 Product [* * *]. For purposes of calculating the Development Milestone Payments and Commercialization Milestone Payments, a Licensed Product is [* * *] if it [* * *]. For clarity, if a Licensed Product is [* * *], that [* * *] would be considered a [* * *].

9.5 Payment Terms.

(a) **Development Milestone Payments**. BeiGene shall provide AssemblyBio with notice of the achievement of each Development Milestone Event within [* * *] thereafter and make the corresponding Development Milestone Payment within [* * *] after such achievement.

(b) **Commercialization Milestone Payments and Royalty Payments**. During the Term, following the First Commercial Sale of a Licensed Product, BeiGene shall furnish to AssemblyBio a written report for each Calendar Quarter showing the Net Sales by Licensed Product sold by BeiGene and its Affiliates and sublicensees during the reporting Calendar Quarter and the Licensed Product royalties payable under this Agreement in sufficient detail to allow AssemblyBio to verify the amount of Licensed Product royalties paid by BeiGene with respect to such Calendar Quarter. Each such report shall include, on a region-by-region and Licensed Product-by-Licensed Product basis, (i) the total gross amount invoiced for Licensed Product sold, (ii) the Net Sales of each Licensed Product and the applicable deductions made to

determine such Net Sales of Licensed Products (by category, as such deductions are set forth under Section 1.60), (iii) a calculation of the royalty payment for each Licensed Product (in USD) payable (including any royalty reduction made in accordance with Section 9.6(c)), and (iv) the royalty payment in total for all Licensed Products and the manner and basis for any currency conversion in accordance with Section 9.8, and shall specify if each Commercialization Milestone Event is achieved during such Calendar Quarter. Such reports shall be due no later than [* * *] following the end of each Calendar Quarter; *provided* that, within [* * *] following the end of each Calendar Quarter, BeiGene shall provide AssemblyBio with a good-faith estimate of the payment amounts to be set forth in such reports to follow. The corresponding Commercialization Milestone Payment(s) and Licensed Product royalties shown to have accrued by each report provided under this Section 9.5(b) shall be due and payable on the date such report is due.

9.6 Royalty Payments to AssemblyBio.

(a) **Royalty Rates**. In further consideration of AssemblyBio's grant of the rights and licenses to BeiGene hereunder, BeiGene shall, during each applicable Royalty Term, pay to AssemblyBio a tiered royalty on Net Sales [* * *] in the Territory for each Calendar Year, at the percentage rates set forth below (subject to Section 9.6(c)):

Calendar Year, Net Sales [* * *] **in the Territory**	**Royalty Rate**
1.≤ USD [* * *]	[* * *]%
2.> USD [* * *] - ≤ USD [* * *]	[* * *]%
3.>USD [* * *] - ≤ USD [* * *]	[* * *]%
4.> USD [* * *] - ≤ USD [* * *]	[* * *]%
5.> USD [* * *]	[* * *]%

By way of illustration, assume in a Calendar Year that (i) Net Sales of [* * *] in the Territory in USD total [* * *] USD ($[* * *]) and (ii) no adjustments or deductions to payments under Section 9.6(c) apply. The total royalties due and payable by BeiGene to AssemblyBio for such Net Sales of [* * *] would be [* * *] USD ($[* * *]), calculated as follows:

$[* * *] x [* * *] % =	$[* * *]
$[* * *] x [* * *] % =	$[* * *]
$[* * *] x [* * *] % =	$[* * *]
$[* * *] x [* * *] % =	$[* * *]
$[* * *] x [* * *] % =	$[* * *]
Total Royalty =	$[* * *]

(b) **Royalty Term**. The royalty payments payable under this Section 9.6 shall be payable on a Licensed Product-by-Licensed Product and region-by-region basis from the First Commercial Sale of such Licensed Product in such region in the Territory until the latest of: (i)

the [* * *] anniversary of the date of the First Commercial Sale of such Licensed Product in such region; (ii) the expiration of the last Valid Claim (including any patent term adjustments or extensions) within the AssemblyBio Patent Rights that Covers such Licensed Product in such region; and (iii) [* * *] for such Licensed Product in such region (the "**Royalty Term**").

(c) **Royalty Reductions**.

(i) **No Valid Claim**. Subject to Section 9.6(c)(iv), on a Licensed Product-by-Licensed Product and region-by-region basis, if there is no Valid Claim within the AssemblyBio Patent Rights that Covers such Licensed Product in a given region in the Territory, then, commencing in the first Calendar Quarter after the date on which this Section 9.6(c)(i) applies and continuing for each Calendar Quarter thereafter for so long as there is no Valid Claim that Covers such Licensed Product in such region, the applicable royalty rate that would otherwise be owed on such Net Sales of such Licensed Product in such region under Section 9.6(a) will be reduced by [* * *].

(ii) **Generic Product**. If a Licensed Product is generating Net Sales in the Field in a region in the Territory during the applicable Royalty Term at a time when one or more Generic Products with respect to such Licensed Product is being sold in such region, then the royalty rate applicable to Net Sales of such Licensed Product in such region in such Calendar Quarter shall be reduced by (A) [* * *] in any Calendar Quarter that BeiGene can demonstrate that [* * *], or (B) [* * *] in any Calendar Quarter that BeiGene can demonstrate that [* * *]. BeiGene will promptly notify AssemblyBio upon BeiGene becoming aware of the entry of such Generic Product(s), which notice will specify the applicable Generic Product and its Indication, the applicable region in the Territory, and the [* * *] of the Generic Products in such region (in each case, to the extent then known by BeiGene).

(iii) **Third Party Payments**. With respect to any Third Party License entered into by BeiGene pursuant to Section 14.5 for a Licensed Product in a region (for licenses in connection with the Licensed Compound(s) in such Licensed Products but not with respect to Other Components of a Combination Product), and during any Calendar Quarter in which BeiGene makes royalty payments to the applicable Third Party, BeiGene may credit against the royalty payments payable to AssemblyBio pursuant to Section 9.6(a) with respect to such Licensed Product in such region in such Calendar Quarter up to [* * *] for which BeiGene is responsible under such Third Party License.

(iv) **Royalty Floor**. In no event will the aggregate amount of royalty payments due to AssemblyBio for a Licensed Product in a region in the Territory in any given Calendar Quarter during the Royalty Term for such Licensed Product in such region be reduced to less than [* * *] of the amount that otherwise would have been due and payable to AssemblyBio in such Calendar Quarter for such Licensed Product in such region but for the reductions set forth in Sections 9.6(c)(i), (ii) and (iii) (the "**Royalty Floor**"); *provided* that, subject always to the Royalty Floor, [* * *].

(v) **COGM Adjustment**. If the Fully Burdened Manufacturing Cost of a Licensed Product is higher than [* * *], then [* * *] of the percent Fully Burdened Manufacturing Cost [* * *] will be [* * *]. By way of example, if [* * *] and the Fully Burdened Manufacturing

Cost is [* * *], then the [* * *] would be [* * *]. If subsequently Fully Burdened Manufacturing Cost are reduced to [* * *], the [* * *].

(vi) **Compulsory Licenses**. If a compulsory license is granted to a Third Party with respect to a Licensed Product in any region in the Territory, to the extent BeiGene is compensated on a royalty basis with a royalty rate lower than the royalty rates provided by Section 9.6(a) (as adjusted per Sections 9.6(c)(i), (ii) (iii) and (v)), the royalty rate to be paid by BeiGene on Net Sales made pursuant to such compulsory license in such region under Section 9.6(a) will be reduced to the rate payable by the compulsory licensee. For purposes of the foregoing, a "compulsory license" means, with respect to a Licensed Product in a country or territory, a license or rights granted to a Third Party by a governmental agency within such country or territory to sell or offer for sale such Licensed Product in such country or territory under any Patent Rights or Know-How owned or Controlled by either Party or its Affiliates, without direct or indirect authorization from such Party or its Affiliates.

9.7 Payments to Third Parties. Except as expressly set forth herein, each Party shall be solely responsible for any payments due to Third Parties under any agreement entered into by such Party with respect to the Licensed Product, as a result of activities hereunder.

9.8 Payment Currency; Exchange Rate. All payments to be made under this Agreement shall be made in USD. Payments to AssemblyBio shall be made by electronic wire transfer of immediately available funds to the account of AssemblyBio, as designated in writing to BeiGene. If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion shall be made in a manner consistent with BeiGene's normal practices used to prepare its audited financial statements for external reporting purposes; *provided* that such practices use a widely accepted source of published exchange rates.

9.9 Late Payments. Any payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [* * *] percentage points above the prime rate as published by *The Wall Street Journal* or any successor thereto on the first day of each Calendar Quarter in which such payments are overdue or (b) the maximum rate permitted by Applicable Laws; in each case calculated on the number of days such payment is delinquent, compounded monthly.

9.10 Records and Audit Rights.

(a) **Records**. Each Party will keep (and will cause its Affiliates and sublicensees to keep) complete, true and accurate books and records in sufficient detail for the other Party to determine payments due to such other Party under this Agreement, including Licensed Product royalty payments and for each Party to calculate Development and Regulatory Costs hereunder. Each Party will keep such books and records for at least [* * *] following the end of the Calendar Year to which they pertain (or a longer period that may be required by Applicable Laws or the applicable Accounting Standard), in accordance with the applicable Accounting Standard. BeiGene will keep such books and records in accordance with the record keeping requirements in Section 6.3 of Exhibit 2.8.

(b) **Audit Rights**.

(i) Each Party (the "**Auditing Party**") shall have the right during the [* * *] period described in Section 9.10(a) to (A) appoint at its expense an independent certified public accountant of nationally recognized standing (the "**Accounting Firm**") reasonably acceptable to the other Party (the "**Audited Party**") to audit the relevant records of the Audited Party and its Affiliates to verify that the amount of such payments were correctly determined and/or (B) require the Audited Party to (1) appoint such an Accounting Firm to conduct such an audit of the applicable sublicensee and (2) provide the results of such audit to the Auditing Party. The Audited Party and its Affiliates shall each make its records available for audit by the Accounting Firm during regular business hours at such place or places where such records are customarily kept, upon reasonable notice from the Auditing Party, solely to verify the payments hereunder were correctly determined. Such audit right shall not be exercised by the Auditing Party more than once in any Calendar Year nor more than once with respect to sales of a particular Licensed Product in a particular period and may cover a period ending not more than [* * *] prior to the date of such request. All records made available for audit pursuant to this Section 9.10(b) shall be deemed to be Confidential Information of the Audited Party. The results of each audit, if any, shall be binding on both Parties. If the amount of any payment hereunder was underreported, the Audited Party shall promptly (but in any event no later than [* * *] after its receipt of the Accounting Firm's report so concluding) make payment to the Auditing Party of the underreported amount. The Auditing Party shall bear the full cost of an audit that it conducts pursuant to this Section 9.10(b) unless such audit discloses an under reporting by the Audited Party of more than [* * *] of the aggregate amount of the payments hereunder reportable in any Calendar Year, in which case the Audited Party shall reimburse the Auditing Party for the reasonable audit fees for such audit, in addition to paying the underreported amount.

(ii) The Accounting Firm will disclose to the Auditing Party only whether the payments or costs subject to such audit are correct or incorrect and the specific details concerning any discrepancies. No other information regarding the results of such audit will be provided to the Auditing Party without the prior consent of the Audited Party. The Audited Party is entitled to require the Accounting Firm to execute a reasonable confidentiality agreement prior to commencing any such audit. The Accounting Firm shall provide a copy of its report and findings to the Audited Party.

9.11 Taxes and Blocked Currency

(a) **Taxes**. Each Party shall be responsible for its own tax liabilities arising under this Agreement. Subject to this Section 9.11, AssemblyBio shall be liable for all of its income and other taxes (including interest) ("**Taxes**") imposed upon any payments made by BeiGene to AssemblyBio under this Agreement ("**Agreement Payments**").

(i) **Tax Withholding**. If Applicable Laws require the withholding of Taxes, BeiGene shall make such withholding payments in a timely manner and shall subtract the amount thereof from the Agreement Payments. BeiGene shall promptly (as available) submit to AssemblyBio appropriate proof of payment of the withheld Taxes as well as the official receipts within a reasonable period of time. BeiGene shall provide AssemblyBio reasonable assistance in order to allow AssemblyBio to obtain the benefit of any present or future treaty against double taxation or refund or reduction in Taxes which may apply to the Agreement Payments. Without

limiting the generality of the foregoing, if AssemblyBio is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding Taxes, it may deliver to BeiGene or the appropriate Governmental Authority in the Territory the prescribed forms necessary to reduce the applicable rate of withholding or to relieve BeiGene of its obligation to withhold Taxes. In such case, BeiGene shall apply the reduced rate of withholding, or not withhold, as the case may be, *provided* that BeiGene is in receipt of evidence, in a form reasonably satisfactory to BeiGene (*e.g.*, AssemblyBio's delivery of all applicable documentation) prior to the time that the applicable Agreement Payments are due.

(ii) **Tax Cooperation**. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Law, of withholding Taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding Tax or VAT.

(iii) **Changes in Domicile**. Notwithstanding anything to the contrary set forth in this Agreement, if BeiGene assigns, transfers, or otherwise disposes of some or all of its rights and obligations under this Agreement to any Person and if, as a result of such action, the withholding or deduction of Tax required by Applicable Law with respect to any Agreement Payment is increased, then (A) any amount payable to AssemblyBio under this Agreement will be increased to take into account such withheld Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), AssemblyBio receives an amount equal to the sum it would have received had no such withholding been made, and (B) AssemblyBio shall use Commercially Reasonable Efforts to obtain a foreign Tax credit for U.S. corporate income Tax purposes for any such additional amount paid pursuant to this sentence, upon the receipt of which AssemblyBio will reimburse BeiGene for such additional amount paid and credited within [* * *]. This Section 9.11(a)(iii) shall not apply to the increased tax exposure caused by the following: (1) any Licensed Product is being or will be Manufactured in the Territory pursuant to Section 7.2(d)(i) or 7.3; and (2) BeiGene assigns some or all of its rights and obligations under this Agreement to a BeiGene Affiliate in China pursuant to Section 16.2, only to the extent that BeiGene is unable to obtain Regulatory Approval in China that would allow a BeiGene Affiliate outside of China to Commercialize the Licensed Products in China despite the use of Commercially Reasonable Efforts to obtain the same.

(b) **Blocked Currency**. If by Applicable Law in a region in the Territory, conversion into USD or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then BeiGene shall promptly notify AssemblyBio and, thereafter, amounts accrued in such region under this Article 9 shall be paid to AssemblyBio (or its designee) in such region in local currency by deposit in a local bank designated by AssemblyBio and to the credit of AssemblyBio, unless the Parties otherwise agree.

ARTICLE 10
CONFIDENTIALITY

10.1 Duty of Confidence. During the Term and for [* * *] thereafter, all Confidential Information disclosed by a Disclosing Party to a Receiving Party hereunder, including (a) with respect to BeiGene as Receiving Party, AssemblyBio Know-How and (b) with respect to AssemblyBio as Receiving Party, any Know-How within BeiGene IP, shall be maintained in confidence by the Receiving Party and shall not be disclosed to any Third Party or used for any

purpose, *except* as set forth herein, without the prior written consent of the Disclosing Party; *provided*, *however*, that with respect to any Confidential Information that is specifically identified at the time of disclosure to be a trade secret under Applicable Laws, such obligations shall survive the expiration of such [* * *] period for so long as such Confidential Information remains a trade secret. The Receiving Party may only use Confidential Information of the Disclosing Party for purposes of exercising its rights and fulfilling its obligations under this Agreement and may disclose Confidential Information of the Disclosing Party and its Affiliates to employees, agents, contractors, consultants and advisers of the recipient Party and its Affiliates, licensees and sublicensees to the extent reasonably necessary for such purposes; *provided* that such Persons are bound by confidentiality and non-use obligations of the Confidential Information consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party and that the Receiving Party will remain fully responsible for any breach of the confidentiality or non-use obligation by such Persons. Notwithstanding the foregoing, AssemblyBio may disclose the terms of this Agreement, the Development Plans, records and reports hereunder to IURTC to the extent required to comply with the terms and conditions of the Upstream License, *provided* that other than with respect to the terms of this Agreement and the exhibits hereto, AssemblyBio shall redact all information not required to be provided to IURTC pursuant to the Upstream License.

10.2 Exceptions. The obligations under this Article 10 shall not apply to any information to the extent the recipient Party can demonstrate by competent evidence that such information:

(a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Receiving Party or its Affiliates;

(b) was known to, or was otherwise in the possession of, the Receiving Party or its Affiliates, as evidenced by its written records, prior to the time of disclosure by the Disclosing Party;

(c) is disclosed to the Receiving Party or an Affiliate on a non-confidential basis by a Third Party that is entitled to disclose it without breaching any confidentiality obligation to the Disclosing Party or any of its Affiliates; or

(d) is independently developed by or on behalf of the Receiving Party or its Affiliates, as evidenced by its written records, without use of or reference to the Confidential Information disclosed by the Disclosing Party or its Affiliates under this Agreement.

10.3 Authorized Disclosures. Subject to this Section 10.3 and Section 7 of Exhibit 2.8, the Receiving Party may disclose Confidential Information belonging to the other Party to the extent permitted as follows:

(a) such disclosure is deemed necessary by counsel to the Receiving Party to be disclosed to such Receiving Party's attorneys, independent accountants or financial advisors for the sole purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to the Receiving Party, on the condition that such attorneys, independent accountants and financial advisors are bound by confidentiality and non-use obligations consistent with the confidentiality provisions of this Agreement as they apply to the Receiving Party;

(b) disclosure by a Receiving Party or its Affiliates to governmental or other regulatory agencies in order to obtain and maintain Patent Rights consistent with Article 14;

(c) disclosure by a Receiving Party to any Affiliate, or to its or its Affiliates' employees, consultants, contractors, subcontractors, agents or sublicensees on a need-to-know basis in order to enable such Receiving Party to exercise its rights or to carry out its responsibilities under this Agreement, including to any Third Party that is engaged by such Party to perform services in connection with the Development, Manufacture and/or Commercialization of each Licensed Compound and/or any Licensed Products in accordance with this Agreement; *provided*, in each case, that such Persons are bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party and that the Receiving Party will remain fully responsible for the any breach of the confidentiality or non-use obligation by such Persons;

(d) disclosure by BeiGene or a BeiGene Affiliate or sublicensee as reasonably necessary to gain or maintain approval to conduct Clinical Trials for a Licensed Product, to obtain and maintain any Regulatory Approval or Pricing and Reimbursement Approval or to otherwise Develop, Manufacture and Commercialize Licensed Products in the Territory, in accordance with this Agreement;

(e) disclosure by AssemblyBio or an AssemblyBio Affiliate or sublicensee as reasonably necessary to gain or maintain approval to conduct Clinical Trials for a Licensed Product, to obtain and maintain any Regulatory Approval or Pricing and Reimbursement Approval or to otherwise Develop, Manufacture and Commercialize Licensed Products outside the Territory;

(f) disclosure by a Party required in connection with any judicial or administrative process relating to or arising from this Agreement (including any enforcement hereof) or to comply with applicable court orders or governmental regulations (or the rules of any recognized stock exchange or quotation system);

(g) disclosure by a Party to potential or actual investors or potential or actual acquirers or actual or potential sublicensees in connection with due diligence or similar investigations by such Third Parties; *provided*, in each case, that any such potential or actual investor or acquirer or sublicensee agrees to be bound by confidentiality and non-use obligations consistent with those contained in this Agreement as they apply to the Receiving Party, and that the Receiving Party will remain fully responsible for the any breach of the confidentiality or non-use obligation by such Persons; or

(h) disclosure or publications permitted pursuant to the terms of Article 11.

If the Receiving Party is required by judicial or administrative process to disclose Confidential Information that is subject to the non-disclosure provisions of this Article 10, such Receiving Party shall promptly inform the Disclosing Party of the disclosure that is being sought in order to provide the Disclosing Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the Disclosing Party, cooperate in all reasonable respects with the Disclosing Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the Disclosing Party's expense. Confidential Information that is disclosed as permitted by this Section 10.3 shall remain otherwise subject to the confidentiality and non-use

provisions of this Article 10, and the Party disclosing Confidential Information as permitted by this Section 10.3 shall take all steps reasonably necessary, including obtaining an order of confidentiality and otherwise cooperating with the other Party, to ensure the continued confidential treatment of such Confidential Information.

ARTICLE 11
PUBLICATIONS & PUBLICITY

11.1 Publications.

(a) Prior to the issuance of any Publication contemplated by this Section 11.1, the Parties will jointly develop a high-level global publication strategy ("**Global Publication Strategy**") to guide the Parties' publications under this Agreement. The Global Publication Strategy shall be delivered to the JSC for its review, discussion and approval. Thereafter, either Party may propose any amendments to the Global Publication Strategy, which amendments also shall be delivered to the JSC for its review, discussion and approval. Prior to the establishment of the Global Publication Strategy, each Party shall provide to the other Party a copy of any proposed Publication for review and comment, to the extent practicable and not causing any delays in the submission process of such Publication.

(b) BeiGene acknowledges that some of the Clinical Trials are part of a multi-center global study. Accordingly and notwithstanding anything to the contrary herein, BeiGene shall not publish or present the Clinical Trial results, Clinical Data, non-clinical data or any associated results or conclusions of any Clinical Trial from a Joint Global Study until after the first publication or presentation regarding the overall global study is completed by AssemblyBio, such publication to be at the sole discretion of AssemblyBio. Thereafter, BeiGene may publish or disclose such Clinical Data, non-clinical data or any associated results or conclusions of any Joint Global Study to the extent provided in, and in accordance with Section 11.1(c) and the Global Publication Strategy.

(c) BeiGene may publicly present or publish any Clinical Data, non-clinical data or any associated results or conclusions generated by or on behalf of BeiGene pursuant to this Agreement solely to the extent that such data, results and conclusions are specific to the Territory and the Field (each such proposed presentation or publication, a "**BeiGene Publication**"), and subject to the additional limitations set forth in this Article 11. In the event BeiGene desires to publicly present or publish a BeiGene Publication in accordance with the foregoing sentence, BeiGene shall provide AssemblyBio (including the Alliance Manager and all AssemblyBio members of the JSC) with a copy of such proposed BeiGene Publication at least [* * *] prior to the earlier of its presentation or intended submission for publication; *provided* that in the case of abstracts, this period shall be at least [* * *] (such applicable period, the "**Review Period**"). BeiGene agrees that it will not submit or present any BeiGene Publication (i) until AssemblyBio has provided written comments during such Review Period on the material in such BeiGene Publication or (ii) until the applicable Review Period has elapsed without written comments from AssemblyBio, in which case BeiGene may proceed and the BeiGene Publication will be considered approved in its entirety. If BeiGene receives written comments from AssemblyBio during the applicable Review Period, it shall consider the comments of AssemblyBio in good faith, but will retain the sole authority to submit the manuscript for BeiGene Publication; *provided* that BeiGene agrees to (A) delete any Confidential Information of AssemblyBio that AssemblyBio

identifies for deletion in AssemblyBio's written comments, (B) delete any Clinical Data, non-clinical data results, conclusions or other related information that is not specific to the Territory or the Field, or the publication of which AssemblyBio reasonably determines, in its sole discretion, would conflict with the Global Publication Strategy or materially and adversely impact the Licensed Product, and (C) delay such BeiGene Publication for a period of up to an additional [* * *] after the end of the applicable Review Period to enable AssemblyBio to draft and file Patent Rights with respect to any subject matter to be made public in such BeiGene Publication and to which AssemblyBio has the applicable intellectual property rights to file such Patent Rights. BeiGene shall provide AssemblyBio a copy of the BeiGene Publication at the time of the submission or presentation. BeiGene agrees to acknowledge the contributions of AssemblyBio, and the employees of AssemblyBio, in all BeiGene Publications as scientifically appropriate. BeiGene shall require its Affiliates, sublicensees and contractors to comply with the obligations of Section 11.1.

(d) Without limiting Section 11.1(a), AssemblyBio shall have the right to publicly present or publish any Clinical Trial results or Clinical Data, including non-clinical data or any results or conclusions associated therewith (each such proposed presentation or publication, a "**AssemblyBio Publication**" and, collectively with any BeiGene Publication, a "**Publication**"), and subject to the limitations set forth in this Section 11.1(d) and in accordance with the Global Publication Strategy. In the event AssemblyBio desires to publicly present or publish a AssemblyBio Publication that includes data from a Clinical Trial site in the Territory in accordance with the foregoing sentence, AssemblyBio shall provide BeiGene (including the Alliance Manager and all BeiGene members of the JSC) with a copy of such proposed AssemblyBio Publication consistent with the applicable Review Period. AssemblyBio agrees that it will not submit or present any AssemblyBio Publication (i) until BeiGene has provided written comments during such Review Period on the material in such AssemblyBio Publication or (ii) until the applicable Review Period has elapsed without written comments from BeiGene, in which case AssemblyBio may proceed and the AssemblyBio Publication will be considered approved in its entirety. If AssemblyBio receives written comments from BeiGene during the applicable Review Period, it shall consider the comments of BeiGene in good faith, but will retain the sole authority to submit the manuscript for AssemblyBio Publication; *provided* that AssemblyBio agrees to (A) delete any Confidential Information of BeiGene that BeiGene identifies for deletion in BeiGene's written comments and (B) delay such AssemblyBio Publication for a period of up to an additional [* * *] after the end of the applicable Review Period to enable BeiGene to draft and file Patent Rights with respect to any subject matter to be made public in such AssemblyBio Publication and to which BeiGene has the applicable intellectual property rights to file such Patent Rights. AssemblyBio shall provide BeiGene a copy of the AssemblyBio Publication at the time of the submission or presentation. AssemblyBio agrees to acknowledge the contributions of BeiGene, and the employees of BeiGene, in all AssemblyBio Publications as scientifically appropriate. AssemblyBio shall require its Affiliates, sublicensees and contractors to comply with the obligations of this Section 11.1(d).

11.2 Attorney-Client Privilege. In the event of a dispute or potential dispute where the Parties: (a) share a common legal and commercial interest in such disclosure that is subject to attorney work product protections, attorney-client privileges or similar protections and privileges; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact

should either Party become subject to any actual or threatened proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that both the Receiving Party and the Disclosing Party will have the right to assert such protections and privileges, the Parties may negotiate and enter into a common or joint defense agreement. Notwithstanding the foregoing, nothing in this Section 11.2 will apply with respect to a Dispute between the Parties (including their respective Affiliates).

11.3 Publication and Listing of Clinical Trials. Each Party agrees to comply, with respect to the listing of Clinical Trials or the publication of Clinical Trial results with respect to Licensed Products and to the extent applicable to its activities conducted under this Agreement, with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements and settlements entered into by such Party; *provided* that any listings or publications made pursuant to this Section 11.3 shall be considered a Publication hereunder and shall be subject to Section 11.1.

11.4 Publicity.

(a) The Parties have mutually approved a joint press release attached hereto as Exhibit 11.4 with respect to this Agreement and either Party may make subsequent public disclosure of the contents of such press release. Subject to the foregoing, each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed), *provided*, *however*, that neither Party will be prevented from complying with any duty of disclosure it may have pursuant to Applicable Laws or pursuant to the rules of any recognized stock exchange or quotation system, subject to that Party notifying the other Party of such duty and limiting such disclosure as reasonably requested by the other Party (and giving the other Party sufficient time to review and comment on any proposed disclosure).

(b) Notwithstanding Section 11.4(a), AssemblyBio has the right to publicly disclose (i) the achievement of material milestones under this Agreement; (ii) to the extent required by Applicable Laws or by any Securities Regulator (as defined below) and subject to AssemblyBio's compliance with Section 11.4(c), the amount of any payment received by AssemblyBio under this Agreement; (iii) the commencement, completion, material data and key results of Clinical Trials conducted under this Agreement; and (iv) any information relating to a Joint Global Study. After a Publication has been made available to the public, each Party may post such Publication or a link to it on its corporate web site without the prior written consent of the other Party.

(c) The Parties hereby acknowledge and agree that either Party may be required by Applicable Laws to submit a copy of this Agreement to the U.S. Securities and Exchange Commission (the "**SEC**") or any national or sub-national securities regulatory body in any jurisdiction (collectively, the "**Securities Regulators**"). If a Party is required by Applicable Laws to submit a description of the terms of this Agreement to and/or file a copy of this Agreement with any Securities Regulator, such Party agrees to consult and coordinate with the other Party with respect to such disclosure and/or the preparation and submission of a confidential treatment request for this Agreement. Notwithstanding the foregoing, if a Party is required by Applicable Laws to

submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator and such Party has (i) promptly notified the other Party in writing of such requirement and any respective timing constraints, (ii) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure and (iii) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Applicable Laws or the applicable Securities Regulator. If a Party seeks to make a disclosure or filing as set forth in this Section 11.4(c) and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will in good faith consider incorporating such comments.

11.5 Repeat Publicity and Publications. Notwithstanding anything to the contrary in this Article 11, the contents of any press release or other publication that has been reviewed and approved by a reviewing Party in accordance with this Article 11 may be re-released by such reviewing Party or publishing Party without a requirement for re-approval.

ARTICLE 12
REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1 Representations, Warranties of Each Party. Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is a corporation or limited company duly organized, validly existing, and in good standing under the laws of the jurisdiction of formation;

(b) it has full corporate power and authority to execute, deliver, and perform this Agreement, and has taken all corporate action required by Applicable Laws and its organizational documents to authorize the execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement;

(c) this Agreement constitutes a valid and binding agreement enforceable against it in accordance with its terms (*except* as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is considered in a proceeding at law or in equity); and

(d) the execution and delivery of this Agreement and all other instruments and documents required to be executed pursuant to this Agreement, and the consummation of the transactions contemplated hereby do not and shall not (i) conflict with or result in a breach of any provision of its organizational documents, (ii) result in a breach of any agreement to which it is a party, or (iii) violate any Applicable Laws.

12.2 Representations and Warranties of AssemblyBio. AssemblyBio represents and warrants to BeiGene as of the Effective Date that:

(a) Exhibit 12.2(a) sets forth a complete and accurate list of all AssemblyBio Patent Rights Controlled by AssemblyBio as of the Effective Date that Cover the Listed Compounds in the Territory (the "**Scheduled Patent Rights**").

(b) AssemblyBio owns or is the exclusive licensee of all right, title, and interest in and to the Scheduled Patent Rights;

(c) AssemblyBio has the right under the Scheduled Patent Rights to grant the License to BeiGene, and it has not granted any license or other right under the Scheduled Patent Rights that is inconsistent with the License;

(d) neither AssemblyBio nor any of its Affiliates has granted any mortgage, pledge, claim, security interest, encumbrance, lien or other charge of any kind on the Scheduled Patent Rights, and the Scheduled Patent Rights are free and clear of any mortgage, pledge, claim, security interest, encumbrance, lien or charge of any kind, in each case that would adversely affect the rights granted to BeiGene herein;

(e) there are no claims, judgments or settlements against AssemblyBio pending, or to AssemblyBio's knowledge, threatened that invalidate or seek to invalidate any Scheduled Patent Rights;

(f) AssemblyBio is not a party to any agreement with any governmental entity or an agency thereof pursuant to which such governmental entity or such agency provided funding for the development of any of the Scheduled Patent Rights and which gives such governmental entity or such agency any rights to any Scheduled Patent Rights that conflicts with, or limits the scope of, the License granted to BeiGene hereunder;

(g) there is no pending litigation, nor has AssemblyBio received any written notice from any Third Party, asserting or alleging that the Development, Manufacture or Commercialization of the Licensed Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party;

(h) to AssemblyBio's knowledge, none of the Scheduled Patent Rights is the subject of any interference proceeding, *inter partes* review or post-grant review and there is no pending or threatened action, suit, proceeding or claim by a Third Party challenging AssemblyBio's ownership rights in, or the validity or scope of, any Scheduled Patent Rights;

(i) there are no pending or, to its knowledge, no threatened (in writing), adverse actions, suits or proceedings against AssemblyBio involving the Scheduled Patent Rights or Licensed Product;

(j) to its knowledge, the AssemblyBio IP includes all Know-How Controlled by AssemblyBio or its Affiliates that is necessary or reasonably useful to Develop, Manufacture and Commercialize each Licensed Compound and/or Licensed Product in the Field in the Territory

as such Development, Manufacture and Commercialization is currently being conducted by AssemblyBio;

(k) to its knowledge, AssemblyBio has complied with all Applicable Laws applicable to (i) the prosecution and maintenance of the Scheduled Patent Rights and (ii) its Development and Manufacture of Licensed Products in the Field;

(l) to its knowledge, there are no acts or omissions of AssemblyBio that would constitute inequitable conduct, fraud, or misrepresentation to the applicable patent office with respect to any Scheduled Patent Rights;

(m) except as set forth under Exhibit 12.2(m), (i) AssemblyBio has obtained, or caused its Affiliates to obtain, assignments from the inventors of all rights and embodiments in and to the Scheduled Patent Rights that are solely owned by AssemblyBio or its Affiliates, (ii) to its knowledge, all such assignments are valid and enforceable, and (iii) the inventorship of the Scheduled Patent Rights that are solely owned by AssemblyBio or its Affiliates is properly identified on each issued patent or patent application in such Scheduled Patent Rights;

(n) AssemblyBio and its Affiliates have used reasonable and diligent efforts consistent with industry practices to protect the secrecy, confidentiality and value of all AssemblyBio Know-How that constitutes trade secrets under Applicable Laws;

(o) AssemblyBio has provided to BeiGene all material documentation, data, and information under its control requested by BeiGene relating to each Licensed Compound and the use thereof in the Field. Without limiting the foregoing, AssemblyBio has provided to BeiGene complete and accurate copies of (i) all existing material Regulatory Submissions made by AssemblyBio or its Affiliate in the Territory or the United States (the "**Existing Regulatory Materials**"), and (ii) all other material correspondence to/from any Regulatory Authority in the Territory or the United States controlled by AssemblyBio, in each case related to each Licensed Compound or any Licensed Product. Other than the Existing Regulatory Materials, neither AssemblyBio nor any of its Affiliates has, as of the Effective Date, obtained or filed any INDs or any other form of regulatory application with Regulatory Approvals for marketing, for each Licensed Compound or any Licensed Product in the Territory or the United States. The Existing Regulatory Materials are, to the knowledge of AssemblyBio, in good standing, and neither AssemblyBio nor any of its Affiliates has received any notice in writing from any Regulatory Authority that the Existing Regulatory Materials are not currently in, or may not remain in, good standing with the applicable Regulatory Authority;

(p) AssemblyBio has provided to BeiGene all material adverse event information with respect to each Licensed Compound or any Licensed Product known to AssemblyBio or its Affiliates; and

(q) The Upstream License is the only agreement by and between AssemblyBio and any Third Party that provides for the license to AssemblyBio of any Know-How or Patent Rights that are included as part of the AssemblyBio IP. BeiGene acknowledges that AssemblyBio has provided BeiGene with the copy of the Upstream License prior to the Effective Date. Without limiting the generality of the foregoing, the Upstream License is in full force and effect and is the valid and binding obligation of AssemblyBio, enforceable in accordance with its terms, and is

binding on IURTC. AssemblyBio has not materially breached and is not currently in material breach of its obligations under the Upstream License in a manner that has, or would reasonably be expected to have, a material adverse effect on the rights granted to BeiGene under this Agreement, and to AssemblyBio's knowledge, IURTC has not materially breached, and is not currently in material breach of, its obligations under the Upstream License.

12.3 Representations and Warranties of BeiGene. BeiGene represents and warrants to AssemblyBio as of the Effective Date that:

(a) there are no legal claims, judgments or settlements against or owed by BeiGene or any of its Affiliates, or pending or, to BeiGene's knowledge, threatened, legal claims or litigation, in each case, relating to antitrust, anti-competition, anti-bribery or corruption violations;

(b) each of BeiGene and its Affiliates is not, and has not been, debarred or disqualified by any Regulatory Authority; and none of BeiGene or its Affiliates' employees or contractors who will be involved in the Development, Manufacture or Commercialization of the Licensed Product are, or have been, debarred or disqualified by any Regulatory Authority;

(c) BeiGene has sufficient financial wherewithal to (i) perform all of its obligations pursuant to this Agreement, and (ii) meet all of its obligations that come due in the ordinary course of business; and

(d) BeiGene has or can readily obtain sufficient technical, clinical, and regulatory expertise to perform all of its obligations pursuant to this Agreement, including its obligations relating to Development, manufacturing, Commercialization, and obtaining Regulatory Approval.

12.4 Covenants of BeiGene. BeiGene covenants to AssemblyBio that:

(a) in the course of performing its obligations or exercising its rights under this Agreement, BeiGene shall comply with all Applicable Laws, including, as applicable, cGMP, GCP, and GLP standards;

(b) BeiGene will conduct its obligations with respect to the Global Development Plan and the Territory Development Plan in strict adherence with the study design set forth in the Global Development Plan and the Territory Development Plan, as may be amended from time to time;

(c) BeiGene and its Affiliates will not employ any employees or use any contractors in the Development, Manufacture or Commercialization of the Licensed Product who are, or have been, debarred or disqualified by any Regulatory Authority;

(d) BeiGene will only engage Clinical Trial sites under the Territory Development Plan and the Global Development Plan that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the applicable Regulatory Authority;

(e) BeiGene and its Affiliates will obtain necessary consents, and sufficient rights, title and interests in the Clinical Data and Regulatory Submissions to grant the right of reference or other right of use to AssemblyBio under Sections 5.9 and 6.3;

(f) except as otherwise expressly permitted in this Agreement, commencing on the Effective Date and continuing until the end of the Term, BeiGene and its Affiliates will not (i) assign or otherwise transfer ownership of any BeiGene IP or BeiGene Collaboration IP, *except* to the extent such assignment or transfer does not conflict with or adversely affect any of the licenses granted to AssemblyBio hereunder, or (ii) grant to any Third Party any license rights to any BeiGene IP or BeiGene Collaboration IP in the Territory if such license grant conflicts with any of the licenses granted to AssemblyBio hereunder;

(g) BeiGene shall comply with all Applicable Upstream License Provisions; and

(h) At such times as BeiGene is serving as regulatory agent pursuant to Section 6.1, (i) BeiGene or its Affiliate who will serve as AssemblyBio's regulatory agent in the Territory will at all times meet all qualification requirements under Applicable Laws in all material respects to be AssemblyBio's regulatory agent in the Territory as contemplated by this Agreement, and (ii) BeiGene will promptly notify AssemblyBio (A) of any significant change to these qualification requirements of which it becomes aware and (B) if BeiGene or its Affiliate may not meet these requirements, upon receiving any notice from any Regulatory Authority or Third Party indicating or otherwise becoming aware of such fact.

12.5 Covenants of AssemblyBio. AssemblyBio covenants to BeiGene that:

(a) in the course of performing its obligations or exercising its rights under this Agreement, AssemblyBio shall comply with all Applicable Laws, including, as applicable, cGMP, GCP, and GLP standards;

(b) AssemblyBio will conduct its obligations with respect to the Global Development Plan in strict adherence with the study design set forth in the Global Development Plan, as may be amended from time to time;

(c) AssemblyBio will only engage Clinical Trial sites under the Global Development Plan that conduct all Clinical Trials in compliance with Applicable Laws, including GCP and the ICH Guidelines, and are approved by the applicable Regulatory Authority;

(d) AssemblyBio and its Affiliates will not employ any employees or use any contractors in the Development or Manufacture of the Licensed Product who are, or have been, debarred or disqualified by any Regulatory Authority;

(e) AssemblyBio and its Affiliates will obtain necessary consents, and sufficient rights, title and interests in the Clinical Data and Regulatory Submissions to grant the right of reference or other right of use to BeiGene under Sections 5.9 and 6.3;

(f) except as otherwise expressly permitted in this Agreement, commencing on the Effective Date and continuing until the end of the Term, AssemblyBio and its Affiliates will

not (i) assign or otherwise transfer ownership of any AssemblyBio Patent Rights or AssemblyBio Know-How in the Territory, *except* to the extent such assignment or transfer does not conflict with or adversely affect any of the Licenses granted to BeiGene hereunder, or (ii) grant to any Third Party any license rights to any AssemblyBio Patent Rights or AssemblyBio Know-How in the Territory if such license grant conflicts with any of the Licenses granted to BeiGene hereunder;

(g) AssemblyBio and its Affiliates shall be responsible for any payments under the Upstream License resulting from the Development, Manufacture, or Commercialization of the Licensed Products in the Field in the Territory under this Agreement; and

(h) AssemblyBio and its Affiliates shall remain in compliance with the Upstream License and shall not terminate, amend, waive or otherwise modify (or consent to any of the foregoing) its rights under the Upstream License in any manner that would materially adversely affect the rights or License granted to BeiGene hereunder or increase or generate any new payment obligation under the Upstream License that would apply to BeiGene, without BeiGene's express written consent. If AssemblyBio or any of its Affiliates receives any notice or other communication that IURTC intends to terminate the Upstream License or the Upstream License otherwise terminates, then AssemblyBio shall provide a written notice to BeiGene as soon as possible, and in any event no later than [* * *] after receipt of such notice or communication or other termination, as applicable.

12.6 NO OTHER WARRANTIES. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 12, (A) NO REPRESENTATION, CONDITION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF ASSEMBLYBIO OR BEIGENE; AND (B) ALL OTHER CONDITIONS AND WARRANTIES WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE ARE EXPRESSLY EXCLUDED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

12.7 Compliance with Anti-Corruption Laws.

(a) Notwithstanding anything to the contrary in this Agreement, each Party agrees, on behalf of itself, its Affiliates, and its and their officers, directors, employees, authorized agents, representatives and consultants, sublicensees and subcontractors (collectively, the "**Representatives**") that:

(i) it and its Representatives shall not, in the performance of this Agreement, perform any actions that are prohibited by local and other anti-corruption laws (including the provisions of the United States Foreign Corrupt Practices Act and equivalent Applicable Laws in the Territory, collectively "**Anti-Corruption Laws**") that may be applicable to one or both Parties;

(ii) it and its Representatives shall adhere to its own internal anti-corruption policies and shall not, in the performance of this Agreement, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other Third Party with the purpose of

influencing decisions related to either Party or its business in a manner that would violate Anti-Corruption Laws;

(iii) it and its Representatives shall not, directly or indirectly, solicit, receive or agree to accept any payment of money or anything of value in violation of the Anti-Corruption Laws;

(iv) it will (A) promptly provide written notice to the other Party of any violations of Anti-Corruption Laws by such Party, its Affiliates or its and their respective Representatives that are performing under of this Agreement of which it becomes aware; and (B) upon the request of the other Party (which such request may be made no more frequently than once per Calendar Year), verify in writing that to the best of its knowledge, there have been no violations of Anti-Corruption Laws by such Party, its Affiliates or its and their respective Representatives that are performing under this Agreement, or shall provide details of any exception to the foregoing; and

(v) it shall maintain records (financial and otherwise) and supporting documentation related to the subject matter of this Agreement in order to document or verify compliance with the provisions of this Section 12.7, and upon request of the other Party, up to one time per Calendar Year and upon reasonable advance notice, shall provide the other Party or its representative with access to such records for purposes of verifying compliance with the provisions of this Section 12.7.

(b) Each Party represents and warrants that, to its knowledge, neither such Party nor any of its Representatives or other Third Parties acting on behalf of such Party or any of its Affiliates:

(i) has taken any action in violation of any applicable Anti-Corruption Laws; or

(ii) has offered, paid, given, promised to pay or give, or authorized the payment or gift of anything of value, directly or indirectly, to any Public Official, for the purposes of:

(1) influencing any act or decision of any Public Official in his or her official capacity;

(2) inducing such Public Official to do or omit to do any act in violation of his or her lawful duty;

(3) securing any improper advantage; or

(4) inducing such Public Official to use his or her influence with a government, governmental entity, or commercial enterprise owned or controlled by any government (including state-owned or controlled veterinary, laboratory or medical facilities) in obtaining or retaining any business whatsoever.

(c) Each Party further represents and warrants that, as of the Effective Date, none of its Representatives or agents acting on behalf of such Party or any of its Affiliates, is a Public Official.

(d) For purposes of this Section 12.7, "**Public Official**" means (i) any officer, employee or representative of any regional, federal, state, provincial, county or municipal government or government department, agency or other division; (ii) any officer, employee or representative of any commercial enterprise that is owned or controlled by a government, including any state-owned or controlled veterinary, laboratory or medical facility; (iii) any officer, employee or representative of any public international organization, such as the African Union, the International Monetary Fund, the United Nations or the World Bank; (iv) candidates of political positions, officers or employees of political parties, or individuals working for such officers or employees; and (v) any person acting in an official capacity for any government or government entity, enterprise or organization identified above.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by BeiGene. BeiGene shall indemnify and hold harmless AssemblyBio, its Affiliates, and their respective directors, officers, employees, contractors, agents and assigns (individually and collectively, the "**AssemblyBio Indemnitee(s)**") from and against all losses, liabilities, damages and expenses (including reasonable attorneys' fees and costs) (individually and collectively, "**Losses**") incurred in connection with any claims, demands, actions or other proceedings by any Third Party (individually and collectively, "**Claims**") to the extent arising from (a) the Development, Manufacture or Commercialization of the Licensed Products by or on behalf of BeiGene or any of its Affiliates or sublicensees, including product liability Claims, in the Territory, (b) BeiGene's actions (or omissions) in the performance of its obligations with respect to Regulatory Approvals, Regulatory Submissions and interactions with Regulatory Authorities, in each case as the authorized regulatory agent of record for AssemblyBio in the Territory, (c) BeiGene's actions (or omissions) in the performance of its obligations with respect to Regulatory Approvals, Regulatory Submissions and interactions with Regulatory Authorities, in each case, with respect to the Licensed Products in the Territory, (d) the gross negligence or willful misconduct of BeiGene or its Affiliates or sublicensees, (e) BeiGene's breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in this Agreement, or (f) the failure of BeiGene or its Affiliates or sublicensees to abide by any Applicable Laws, in each case of clauses (a) through (f) above, *except* to the extent such Losses or Claims arise out of an AssemblyBio Indemnitee's gross negligence or willful misconduct, breach of this Agreement, or material failure to abide by any Applicable Laws.

13.2 Indemnification by AssemblyBio. AssemblyBio shall indemnify and hold harmless BeiGene, its Affiliates, and their directors, officers, employees, contractors, agents and assigns (individually and collectively, the "**BeiGene Indemnitee(s)**") from and against all Losses incurred in connection with Claims against such BeiGene Indemnitee to the extent arising from (a) the Development, Manufacture or Commercialization of the Licensed Products by or on behalf of AssemblyBio or any of its Affiliates or sublicensees (not including BeiGene or its Affiliates or sublicensees), including product liability Claims, outside the Territory, (b) the Development or Manufacture of the Licensed Products by or on behalf of AssemblyBio or any of its Affiliates or sublicensees (not including BeiGene or its Affiliates or sublicensees) in the Territory as contemplated by this Agreement, (c) AssemblyBio's actions (or omissions) in the performance of its obligations with respect to Regulatory Approvals, Regulatory Submissions and interactions with Regulatory Authorities, in any case, with respect to the Licensed Products, (d) the gross negligence or willful misconduct of AssemblyBio or its Affiliates hereunder, (e) AssemblyBio's breach of any of its representations or warranties made in or pursuant to this Agreement or any covenants or obligations set forth in this Agreement, or (f) failure of AssemblyBio or its Affiliates to abide by any Applicable Laws in its performance hereunder, in each case of clauses (a) through (f) above, *except* to the extent such Losses or Claims arise out of any of a BeiGene Indemnitee's gross negligence or willful misconduct, breach of this Agreement or material failure to abide by any Applicable Laws.

13.3 Indemnification Procedure. If either Party is seeking indemnification under Sections 13.1 or 13.2 (the "**Indemnified Party**"), it shall inform the other Party (the "**Indemnifying Party**") of the Claim giving rise to the obligation to indemnify pursuant to such Section within [* * *] after receiving written notice of the Claim (it being understood and agreed,

however, that the failure or delay by an Indemnified Party to give such notice of a Claim shall not affect the indemnification provided hereunder *except* to the extent the Indemnifying Party shall have been actually and materially prejudiced as a result of such failure or delay to give notice). The Indemnifying Party shall have the right to assume the defense of any such Claim for which it is obligated to indemnify the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and the Indemnifying Party's insurer as the Indemnifying Party may reasonably request, and at the Indemnifying Party's cost and expense. The Indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any Claim that has been assumed by the Indemnifying Party. Neither Party shall have the obligation to indemnify the other Party in connection with any settlement made without the Indemnifying Party's written consent, which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnifying Party will not admit liability of the Indemnified Party or otherwise enter into a settlement adverse to the interest of the Indemnified Party without the Indemnified Party's prior written consent, which consent will not be unreasonably withheld, conditioned, or delayed. If the Parties cannot agree as to the application of Section 13.1 or 13.2 as to any Claim, pending resolution of the dispute pursuant to Section 16.6, the Parties may conduct separate defenses of such Claims, with each Party retaining the right to Claim indemnification from the other Party in accordance with Section 13.1 or 13.2 upon resolution of the underlying Claim.

13.4 Mitigation of Loss. Each Indemnified Party shall take and shall procure that its Affiliates take all such reasonable steps and action as are reasonably necessary in order to mitigate any Losses (or potential losses or damages) under this Article 13. Nothing in this Agreement shall or shall be deemed to relieve any Party of any common law or other duty to mitigate any losses incurred by it.

13.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 13.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTIONS 13.1 OR 13.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO CONFIDENTIALITY OR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTIONS 2.6 AND 2.7.

13.6 Insurance. Each Party shall procure and maintain insurance, including product liability insurance, with respect to its activities hereunder and which is consistent with normal business practices of prudent companies similarly situated at all times during which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold in the Territory and/or outside of the Territory and the requirements set forth in Section 12 of Exhibit 2.8. All such insurance coverage may be maintained through a self-insurance plan that substantially complies with the foregoing limits and requirements and may be satisfied through one or more policies, including an umbrella policy; *provided*, *however*, that the other Party will provide to the requesting Party a letter(s) affirming appropriate self-insurance and/or a certificate of insurance evidencing such coverage in accordance with this Agreement. Each Party will maintain such insurance or self-insurance coverage without interruption during the Term and for a period of [* * *]

thereafter, and, if applicable, will provide certificates and/or letters evidencing such insurance coverage without interruption as reasonably requested during the period of time for which such coverage must be maintained. Each Party will be provided at least [* * *] prior written notice of any cancellation or material decrease in the other Party's insurance coverage limits described above. Notwithstanding the foregoing, either Party's failure to maintain adequate insurance will not relieve that Party of its obligations set forth in this Agreement.

ARTICLE 14
INTELLECTUAL PROPERTY

14.1 Inventions.

(a) **Ownership**. As between the Parties, (i) AssemblyBio shall solely own all AssemblyBio IP and Product-Specific IP, (ii) BeiGene shall solely own all BeiGene IP, and (iii) the ownership of any other Invention shall be determined by inventorship in accordance with the United States patent law. Accordingly, *except* as otherwise provided in this Section 14.1(a), (A) Inventions that are made solely by or on behalf of AssemblyBio and its Affiliates (and all intellectual property rights therein, including the Patent Rights claiming them) shall be owned solely by AssemblyBio ("**AssemblyBio Collaboration IP**"); (B) Inventions that are made solely by BeiGene (and all intellectual property rights therein, including the Patent Rights claiming them, *except* any Product-Specific IP) shall be owned solely by BeiGene ("**BeiGene Collaboration IP**"); and (C) Inventions that are made jointly by the Parties (and all intellectual property rights therein, including the Patent Rights claiming them) shall be owned jointly by the Parties ("**Joint Collaboration IP**"). Product-Specific IP shall be included in the AssemblyBio IP and licensed to BeiGene in the Field in the Territory under Section 2.1.

(b) **Disclosure**. Each Party shall promptly disclose to the other Party all Inventions, including all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, agents, or independent contractors relating thereto, and shall also promptly respond to reasonable requests from the other Party for additional information relating thereto.

(c) **Assignment; Jointly-Owned Inventions**.

(i) BeiGene shall assign and hereby does assign to AssemblyBio all right, title and interest in and to all Product-Specific IP. BeiGene shall take (and cause its Affiliates, sublicensees and their employees, agents, and contractors to take) such further actions reasonably requested by AssemblyBio to evidence such assignment and to assist AssemblyBio in obtaining patent and other intellectual property rights protection for the Product-Specific IP. BeiGene shall obligate its Affiliates, sublicensees and contractors to assign all Product-Specific IP to BeiGene (or directly to AssemblyBio), so that BeiGene can comply with its obligations under this Section 14.1, and BeiGene shall promptly obtain such assignment.

(ii) Subject to the rights granted under and the restrictions set forth in this Agreement, it is understood that neither Party shall have any obligation to account to the other Party for profits, or to obtain any approval of the other Party to license, assign or otherwise exploit any Joint Collaboration IP (or any Patent Rights claiming the same, "**Joint Patent Rights**"), by

reason of joint ownership thereof, and each Party hereby waives any right it may have under the Applicable Law of any jurisdiction to require any such approval or accounting.

14.2 Patent Prosecution.

(a) **AssemblyBio Patent Rights**.

(i) Subject to Section 14.2(c), as between the Parties, AssemblyBio shall have the right to control the Patent Prosecution of all AssemblyBio Patent Rights [* * *].

(ii) AssemblyBio shall (A) provide BeiGene with a reasonable opportunity to consult with AssemblyBio regarding such AssemblyBio Patent Rights in the Territory, and any amendment, submission or response with respect to such AssemblyBio Patent Rights and keep BeiGene reasonably informed of the Patent Prosecution of the AssemblyBio Patent Rights and (B) provide BeiGene with all material correspondence received from any patent authority in connection therewith in sufficient time to allow for review and comment by BeiGene. Further, AssemblyBio shall notify BeiGene of any decision to cease Patent Prosecution or maintenance of any AssemblyBio Patent Rights in the Territory. AssemblyBio will consider BeiGene's comments on Patent Prosecution in good faith but will have final decision-making authority under this Section 14.2(a)(ii).

(b) **BeiGene Patent Rights**. As between the Parties, BeiGene shall have the sole right to control the Patent Prosecution of all BeiGene Patent Rights throughout the world, [* * *].

(c) **Joint Patent Rights**. In the event that any jointly-owned Invention is created hereunder, at either Party's request, the Parties shall discuss a mutually acceptable filing and prosecution strategy for any Joint Patent Rights; *provided* that absent such agreement, AssemblyBio shall control the Patent Prosecution of any Joint Patent Rights, as set forth in this Section 14.2(c). Unless the Parties agree in writing on an alternative arrangement, AssemblyBio shall [* * *] of Patent Prosecution of Joint Patent Rights. AssemblyBio shall (i) provide BeiGene with an opportunity to consult with AssemblyBio regarding such Joint Patent Rights, and any amendment, submission or response with respect to such Joint Patent Rights and keep BeiGene reasonably informed of the Patent Prosecution of the Joint Patent Rights, and (ii) provide BeiGene with all material correspondence received from any patent authority in connection therewith in sufficient time to allow for review and comment by BeiGene. Further, AssemblyBio shall notify BeiGene of any decision to cease Patent Prosecution of any Joint Patent Rights. AssemblyBio will consider BeiGene's comments on Patent Prosecution in good faith but will have final decision-making authority under this Section 14.2(c).

(d) **Cooperation**. Each Party shall provide the other Party all reasonable assistance and cooperation in the Patent Prosecution efforts under this Section 14.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

(e) **Abandonment**. If AssemblyBio decides to cease the Patent Prosecution, or to allow to lapse, any AssemblyBio Patent Rights in the Territory or any Joint Patent Rights, AssemblyBio shall inform BeiGene of such decision promptly and, in any event, so as to provide

BeiGene a reasonable amount of time to meet any applicable deadline to establish or preserve such Patent Rights in such country or region. BeiGene shall have the right, but not the obligation, to assume responsibility for continuing the Patent Prosecution of such Patent Rights in AssemblyBio's name (or both Parties' names, with respect to Joint Patent Rights), [* * *], through patent counsel or agents of its choice and, to the extent that BeiGene assumes such responsibility, AssemblyBio shall promptly deliver to BeiGene copies of all necessary files related to any Patent Rights with respect to which responsibility has been transferred and shall take all actions and execute all documents reasonably necessary for BeiGene to assume such Patent Prosecution activities, [* * *].

14.3 Patent Enforcement.

(a) **Notice**. Each Party shall notify the other within [* * *] of becoming aware of any alleged or threatened infringement by a Third Party of (i) any of the Scheduled Patent Rights or Joint Patent Rights in the Territory or (ii) any of the BeiGene Patent Rights in the Territory, which infringement of such BeiGene Patent Rights adversely affects or is reasonably expected to adversely affect any Licensed Product in the Field in the Territory, and, in each case, any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Rights (collectively "**Product Infringement**"). Each Party shall also notify the other within [* * *] of becoming aware of any alleged or threatened infringement by a Third Party of any Patent Rights that claims BeiGene Collaboration IP ("**BeiGene Collaboration Patent Rights**"), which infringement adversely affects or is reasonably expected to adversely affect any Licensed Product outside of the Territory, including any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Rights (an "**Ex-Territory Infringement**"). For clarity, Product Infringement and Ex-Territory Infringement, in each case, exclude any adversarial Patent Prosecution proceedings.

(b) **Enforcement Rights**.

(i) BeiGene shall have the first right to bring and control any legal action to enforce Scheduled Patent Rights and any substitutions, continuations, continuations-in-part, continued prosecution applications including requests for continued examination, divisional applications and renewals, and all letters patent or certificates of invention granted thereon, and all reissues, reexaminations, extensions (including pediatric exclusivity patent extensions), term restorations, renewals, substitutions, confirmations, registrations, revalidations, revisions and additions of or to any of the foregoing, in each case, in the Territory, or Joint Patent Rights (cumulatively, the "**Enforceable Patent Rights**") against any Product Infringement in the Territory at its sole expense as it reasonably determines appropriate, and BeiGene shall consider in good faith the interests of AssemblyBio in such enforcement of the Enforceable Patent Rights; *provided* that: (A) BeiGene shall keep AssemblyBio reasonably informed about such enforcement; (B) BeiGene shall not take any position with respect to, or compromise or settle, any such Product Infringement in any way that materially and adversely affects the scope, validity or enforceability of any Enforceable Patent Rights, without the prior consent of AssemblyBio, which consent shall not be unreasonably withheld, delayed or conditioned; and (C) if BeiGene does not intend to prosecute or defend a Product Infringement, or ceases to diligently pursue an enforcement with respect to such a Product Infringement, it shall promptly inform AssemblyBio in such a manner that such enforcement will not be prejudiced and Section 14.3(b)(ii) shall apply.

(ii) If BeiGene or its designee fails to abate such Product Infringement in the Territory or to file an action to abate such Product Infringement in the Territory within [* * *] after becoming aware of such Product Infringement, or if BeiGene discontinues the prosecution of any such action after filing without abating such Product Infringement, then AssemblyBio shall have the right to enforce the Enforceable Patent Rights, as applicable, against such Product Infringement in the Territory at its sole expense as it reasonably determines appropriate and shall keep BeiGene reasonably informed with respect to any such enforcement action; *provided* that (A) if BeiGene provides a reasonable rationale for not pursuing or continuing to pursue such Product Infringement (including a substantive concern regarding counter-claims by the infringing Third Party), AssemblyBio shall not pursue any action against such Product Infringement, and BeiGene and AssemblyBio shall discuss in good faith whether to consider the appropriate steps to be taken to address BeiGene's concerns as well as the effect of such Product Infringement on BeiGene and (B) AssemblyBio shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any Enforceable Patent Rights in the Territory without the prior written consent of BeiGene, which consent shall not be unreasonably withheld, delayed or conditioned.

(iii) BeiGene shall have the sole right to bring and control any legal action to enforce BeiGene Patent Rights against any Product Infringement in the Territory at its sole expense as it reasonably determines appropriate, and shall keep AssemblyBio reasonably informed with respect to any such legal action. BeiGene shall not have the right to enforce any AssemblyBio Patent Rights outside of the Territory.

(iv) BeiGene shall have the first right to bring and control any legal action to enforce any BeiGene Collaboration Patent Rights against any Ex-Territory Infringement outside of the Territory at its sole expense as it reasonably determines appropriate, and BeiGene shall consider in good faith the interests of AssemblyBio in such enforcement of the BeiGene Collaboration Patent Rights. If BeiGene or its designee fails to abate such Ex-Territory Infringement outside of the Territory or to file an action to abate such Ex-Territory Infringement outside of the Territory within [* * *] after a written request from AssemblyBio to do so, or if BeiGene discontinues the prosecution of any such action after filing without abating such infringement, then AssemblyBio shall have the right to enforce such BeiGene Collaboration Patent Rights against such Ex-Territory Infringement outside the Territory at its own expense as it reasonably determines appropriate; *provided* that (A) if BeiGene provides a reasonable rationale for not pursuing or continuing to pursue such Ex-Territory Infringement (including a substantive concern regarding counter-claims by the infringing Third Party), AssemblyBio shall not pursue any action against such Product Infringement, and BeiGene and AssemblyBio shall discuss in good faith whether to consider the appropriate steps to be taken to address BeiGene's concerns and (B) AssemblyBio shall not enter into any settlement admitting the invalidity of, or otherwise impairing, any BeiGene Collaboration Patent Rights without the prior written consent of BeiGene which consent shall not be unreasonably withheld, delayed or conditioned.

(c) **Cooperation**. At the request of the Party bringing an action related to Product Infringement or Ex-Territory Infringement, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Laws to pursue such action, at each such Party's sole cost and expense.

(d) **Recoveries**. Any recoveries resulting from an enforcement action relating to a claim of Product Infringement in the Territory or an Ex-Territory Infringement will first be applied to costs and expenses incurred by each Party in connection with such action (including, for this purpose, a reasonable allocation of expenses of internal counsel) (*provided* that if the amount of such recovery is not sufficient to cover all such costs and expenses of each Party, then the amount of the recovery will be proportionately shared by the Parties based on the amount of such costs and expenses incurred by each Party); and with respect to any remaining proceeds, (i) the Parties shall negotiate in good faith an appropriate allocation of such remaining proceeds to reflect the economic interests of the Parties under this Agreement with respect to such Product Infringement and (ii) unless otherwise agreed in subsection (i), [* * *] of such remaining proceeds will be allocated to the enforcing Party and [* * *] of such remaining proceeds will be allocated to the non-enforcing Party.

14.4 Infringement of Third Party Rights.

(a) **Notice**. If any Licensed Product used or sold by BeiGene, its Affiliates or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of any Patent Rights or other intellectual property rights in the Territory that are owned or controlled by such Third Party, BeiGene shall promptly notify AssemblyBio within [* * *] after receipt of such claim or assertion and such notice shall include a copy of any summons or complaint (or the equivalent thereof), including, if applicable, a certified translation into English, received regarding the foregoing. Thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action and may, if appropriate, agree on and enter into a "common interest agreement" wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. The Parties shall assert and not waive the joint defense privilege with respect to any communications between the Parties in connection with the defense of such claim or assertion.

(b) **Defense**. In the event that a claim is brought against either Party alleging the infringement, violation or misappropriation of any Third Party intellectual property right based on the Manufacture, use, sale or importation of the Licensed Products in the Field in the Territory, the Parties shall promptly meet to discuss the defense of such claim, and the Parties shall, as appropriate, enter into a joint defense agreement with respect to the common interest privilege protecting communications regarding such claim in a form reasonably acceptable to the Parties; *provided*, that, unless otherwise agreed by the Parties, BeiGene will have the first right, but not the obligation, to defend and dispose (including through settlement or license) such claim; *provided* that (i) BeiGene will discuss in good faith and coordinate with AssemblyBio in connection therewith and BeiGene will consider in good faith and reasonably address AssemblyBio's input and comments with respect thereto and (ii) BeiGene will not, without the consent of AssemblyBio, enter into any such settlement, consent judgment or other disposition of any action or proceeding that would (A) impose any liability or obligation on AssemblyBio, (B) include the grant of any license, covenant or other rights to any Third Party that would conflict with or reduce the scope of the rights of AssemblyBio with respect to the Licensed Products outside of the Territory or with respect to the AssemblyBio IP, or (C) otherwise adversely affect the rights of AssemblyBio with respect to the Licensed Products outside of the Territory or with respect to the AssemblyBio IP. BeiGene will keep AssemblyBio informed on the status of such defense action, and AssemblyBio will have the right, but not the obligation, to participate and be separately represented in such defense action at its sole option and at its own expense. In the event BeiGene fails to use Commercially Reasonable Efforts

to resolve such Third Party claims, AssemblyBio shall have the right to assume the defense of such claims.

14.5 Third Party In-License. In the event either Party reasonably determines that any Patent Rights owned or controlled by a Third Party are necessary for the Development or Commercialization of the Licensed Product in the Field in the Territory, such Party will so notify the other Party, and shall provide the other Party with the opportunity to review and comment on (a) such Patent Rights as identified as necessary, and (b) the proposed terms and conditions of a license agreement with such Third Party for such Patent Rights (a "**Third Party License**"), and such Party shall consider in good faith any comments received from the other Party. If such Party enters into such Third Party License with the applicable Third Party, such Party will provide the other Party with a true and complete copy of such Third Party License within [* * *] following the execution thereof. In the event AssemblyBio enters into such Third Party License, BeiGene shall [* * *]. In the event BeiGene enters into such Third Party License, BeiGene shall [* * *].

14.6 In-Licensed Patent Rights. Each Party's rights under this Article 14 with respect to the prosecution and enforcement of any In-Licensed Patent Rights shall be subject to the rights of IUTRC under the Upstream License to prosecute and enforce such Patent Rights that are set forth on Exhibit 14.6.

14.7 Patent Term Extensions. BeiGene will reasonably cooperate with AssemblyBio, including providing reasonable assistance to AssemblyBio in its efforts to seek and obtain patent term restoration or supplemental protection certificates or the like or their equivalents in any region in the Territory, where applicable to AssemblyBio Patent Rights, including as may be available to the Parties under the provisions of the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 or comparable laws outside the United States of America, in each case, in connection with any Licensed Product. Notwithstanding anything to the contrary contained herein, if elections with respect to obtaining such patent term restoration or supplemental protection certificates or the like or their equivalents in the Territory are to be made in connection therewith, the Parties will mutually agree upon the election. The requirements of Section 9.7 of Exhibit 2.8 shall also apply to this Agreement.

14.8 Product Trademarks. Subject to Section 8.4(c), BeiGene shall have the right to brand Licensed Products in the Territory using trademarks, logos, and trade names it determines appropriate for such Licensed Products, which may vary by region or within a region (the "**Product Marks**"); *provided*, *however*, that BeiGene shall not (a) use any trademarks or house marks of AssemblyBio (including AssemblyBio's corporate name) or any trademark confusingly similar thereto, or (b) any trademarks or house marks that are inconsistent with the Global Brand Elements, in both cases (a) and (b), without AssemblyBio's prior written consent. BeiGene shall own all rights in the Product Marks in the Territory (excluding any such marks that include, in whole or part, any corporate name or logos of AssemblyBio or its Affiliates or sublicensees) and shall register and maintain the Product Marks in the Territory that it determines reasonably necessary, at BeiGene's cost and expense.

14.9 Patent Marking. BeiGene shall mark all Licensed Products in accordance with Applicable Laws, including the applicable patent marking laws, and shall require all of its Affiliates and sublicensees to do the same. To the extent permitted by Applicable Laws, BeiGene

shall indicate on the product packaging, advertisement and promotional materials that such Licensed Product is in-licensed from AssemblyBio.

ARTICLE 15
TERM AND TERMINATION

15.1 Term. This Agreement shall be effective as of the Effective Date, and shall continue, on a region-by-region and Licensed Product-by-Licensed Product basis, in effect until the expiration of the Royalty Term applicable to such Licensed Product in such region (the "**Term**"). On a region-by-region and Licensed Product-by-Licensed Product basis, upon the natural expiration of the Term as contemplated in this Section 15.1, the License in such region shall become fully paid-up, royalty-free, perpetual, irrevocable and non-exclusive; *provided*, that, any remaining Development Milestone Events or Commercialization Milestones Events that are achieved with respect to a Licensed Product after such expiration shall be and remain subject to BeiGene's obligation to pay the corresponding Development Milestone Payments or Commercialization Milestone Payments (as applicable) in accordance with Sections 9.2 and 9.3, which shall survive such expiration.

15.2 Termination

(a) **Termination by BeiGene for Convenience**. At any time, BeiGene may terminate this Agreement by providing written notice of termination to AssemblyBio, which termination is effective ninety (90) days after the date of the notice.

(b) **Termination upon BeiGene Election**. This Agreement will terminate on a Licensed Compound-by-Licensed Compound basis with respect to ABI-H2158 or ABI-H3733, and such Licensed Compound's corresponding Licensed Products, upon written notice by BeiGene of termination to AssemblyBio after the process outlined under Section 5.2(d).

(c) **Termination for Material Breach**.

(i) If either BeiGene or AssemblyBio is in material breach of any obligation hereunder, the non-breaching Party may give notice to the breaching Party specifying the claimed particulars of such breach (a "**Breach Notification**"). If the Party receiving a Breach Notification fails to cure, or fails to dispute, that material breach on or before [* * *] from the date of the Breach Notification, the Party delivering the Breach Notification may terminate this Agreement.

(ii) If the allegedly breaching Party disputes in good faith the existence, materiality, or cure of the applicable material breach and provides written notice of such dispute to the other Party within the [* * *] period set forth above, then the matter will be addressed under the dispute resolution provisions in Section 16.6 and the termination will not become effective unless and until it has been determined under Section 16.6 that the allegedly breaching Party is in material breach of any of its obligations under this Agreement and has failed to cure the same. During the pendency of such a dispute, all of the terms of this Agreement will remain in effect and the Parties will continue to perform all of their respective obligations hereunder.

(d) **Termination for Patent Challenge**. Notwithstanding anything herein to the contrary, in the event that BeiGene or its Affiliates file or initiate an action challenging (directly or indirectly (*e.g.*, through a Third Party)) in a court or by administrative proceeding seeking the invalidity or unenforceability or seeking to limit the scope of any Scheduled Patent Rights (or their respective counterpart Patent Rights in other jurisdictions), then AssemblyBio, at its discretion, may give notice to BeiGene that AssemblyBio will terminate the License granted to BeiGene under Section 2.1 unless such challenge is withdrawn, abandoned, or terminated (as appropriate) within [* * *] from the date of such notice. In the event that BeiGene or its Affiliate (as the case may be) does not withdraw, abandon or terminate (as appropriate) such challenge within such [* * *] period, AssemblyBio may terminate this Agreement, and BeiGene shall cease all Development and Commercialization of the Licensed Products. For clarity, this Section 15.2(d) does not apply to any counterclaim filed by BeiGene or its Affiliates or sublicensees as defendant in any Scheduled Patent Rights (or their respective counterpart Patent Rights in other jurisdictions) infringement cause of action filed or initiated by AssemblyBio or its Affiliates with respect to a Licensed Product or activities under this Agreement.

(e) **Termination for Insolvency**. Each Party shall have the right to terminate this Agreement upon delivery of written notice to the other Party in the event that (i) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (ii) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [* * *] of its filing, or (iii) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.

(f) **Full Force and Effect During Notice Period**. This Agreement shall remain in full force and effect until the expiration of the applicable termination notice period. For clarity, if any milestone event is achieved or royalty payments become payable under Article 9 during the termination notice period, the corresponding milestone payment or royalty payment, as applicable, is accrued and BeiGene shall remain responsible for the payment of such milestone payment or royalty payment, as applicable, even if the due date of such milestone payment or royalty payment, as applicable, may come after the effective date of the termination.

15.3 Effect of Termination. Except as provided in Section 15.4, if this Agreement is terminated (including due to the exercise of BeiGene Election pursuant to Section 5.2(d)(ii)) the following shall apply:

(a) **License Grant to BeiGene**. The License and all other rights granted by AssemblyBio to BeiGene under the AssemblyBio IP pursuant to this Agreement (including any sublicense with respect to the In-Licensed Patent Rights) shall terminate.

(b) **License Grants to AssemblyBio**. The licenses granted by BeiGene to AssemblyBio pursuant to Section 2.4 shall continue following the effective date of termination and will become a worldwide license. Such license shall be [* * *], except that in the case BeiGene terminates this Agreement pursuant to Section 15.2(c), then such license in the Territory shall be [* * *], *provided* that [* * *]. Except as otherwise provided in this Section 15.3, all other rights and licenses granted by BeiGene to AssemblyBio pursuant to this Agreement shall terminate.

(c) **Sublicenses**. If the License granted to BeiGene terminates as a result of a termination of this Agreement, the terms of this Section 15.3(c) will apply with respect to any sublicense agreement existing as of the effective date of such termination, but only if the applicable sublicensee did not contribute to any material breach of this Agreement that was the cause of the termination by AssemblyBio of this Agreement and is not otherwise in material breach of the applicable sublicense agreement at such time. At the request of a sublicensee in good standing, AssemblyBio will consider in good faith maintaining such sublicense, *provided* that (i) all of such sublicensee's obligations under the applicable sublicense agreement to BeiGene will remain in effect as obligations to AssemblyBio and will be enforceable solely by AssemblyBio as a third party beneficiary; (ii) such sublicensee's rights under the sublicense agreement that do not exceed and are consistent with AssemblyBio's obligations to BeiGene under this Agreement, whether in scope, duration, nature or otherwise, will survive termination; *provided*, that, the foregoing will in no way be interpreted to increase the scope, duration, territory or other aspect of the rights sublicensed to such sublicensee; and (iii) all of BeiGene's rights under such sublicense agreement will remain in effect, may be exercised solely by AssemblyBio and will inure to the exclusive benefit of AssemblyBio.

(d) **Regulatory Submissions**. Upon AssemblyBio's written request to the extent delivered on or before the effective date of termination or within [* * *] thereafter, BeiGene shall provide AssemblyBio with copies of all Regulatory Submissions for Licensed Products. To the extent permissible under Applicable Law, BeiGene shall assign to AssemblyBio or shall provide AssemblyBio with a right of reference with respect to such Regulatory Submissions, as AssemblyBio determines at its reasonable discretion, at BeiGene's cost and expense. The right of reference granted to AssemblyBio under Section 6.3 shall survive during any transition period after the termination of this Agreement before all relevant Regulatory Submissions, Regulatory Approvals and Pricing and Reimbursement Approvals are transferred to AssemblyBio or a separate right of reference is granted pursuant to this Section 15.3(d). In addition, upon AssemblyBio's written request, BeiGene shall, at its cost and expense, provide to AssemblyBio copies of all material related documentation, including material Clinical Data that are held by or reasonably available to BeiGene, its Affiliates or sublicensees. The Parties shall discuss and establish appropriate arrangements with respect to safety data exchange, provided that AssemblyBio will assume all safety and safety database activities no later than [* * *] after termination.

(e) **Trademarks**. BeiGene shall transfer and assign, and shall ensure that its Affiliates transfer and assign, to AssemblyBio, at no cost to AssemblyBio, all Product Marks relating to any Licensed Product and any applications therefor (excluding any such marks that include, in whole or part, any corporate name or logos of BeiGene or its Affiliates or sublicensees). AssemblyBio and its Affiliates and licensees shall have the right to use other identifiers specific to any Licensed Product (*e.g.*, BeiGene compound identifiers). BeiGene shall also transfer to AssemblyBio any in-process applications for generic names for any Licensed Product.

(f) **Inventory**. At AssemblyBio's election and request, BeiGene shall transfer to AssemblyBio or its designee some or all inventory of Licensed Products (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or control of BeiGene, its Affiliates or sublicensees; *provided* that, AssemblyBio will pay BeiGene a price equal to [* * *] for such transferred Licensed Products.

(g) **Wind Down and Transition**. BeiGene shall be responsible, at its own cost and expense, for the wind-down of BeiGene's and its Affiliates' and, subject to Section 15.3(c), its sublicensees' Development, Manufacture and Commercialization activities for Licensed Products. BeiGene shall, and shall cause its Affiliates and, subject to Section 15.3(c), its sublicensees to, reasonably cooperate with AssemblyBio to facilitate orderly transition of the Development, Manufacture and Commercialization of Licensed Products to AssemblyBio or its designee, including (i) assigning or amending as appropriate, upon request of AssemblyBio, any agreements or arrangements with Third Party vendors (including distributors) to Develop, Manufacture, promote, distribute, sell or otherwise Commercialize Licensed Products or, to the extent any such Third Party agreement or arrangement is not assignable to AssemblyBio, reasonably cooperating with AssemblyBio to arrange to continue to provide such services for a reasonable time after termination; and (ii) to the extent that BeiGene or its Affiliate is performing any activities described above in (i), reasonably cooperating with AssemblyBio to transfer such activities to AssemblyBio or its designee and continuing to perform such activities on AssemblyBio's behalf for a reasonable time after termination until such transfer is completed.

(h) **Ongoing Clinical Trial**. If, at the time of such termination, BeiGene or its Affiliates are conducting any Clinical Trials, then, at AssemblyBio's election on a Clinical Trial-by-Clinical Trial basis to the extent delivered on or before the effective date of termination or within the [* * *] period immediately thereafter: (i) to the extent permissible under Applicable Law, BeiGene shall, and shall cause its Affiliates to, cooperate with AssemblyBio to transfer the conduct of such Clinical Trial to AssemblyBio or its designees and complete such transfer promptly and, in any case, within [* * *] after the termination effective date, and AssemblyBio shall assume any and all liability for the conduct of such transferred Clinical Trial after the effective date of such transfer (*except* to the extent arising prior to the transfer date or from any willful misconduct or negligent act or omission by BeiGene, its Affiliates or their respective employees, agents and contractors or their violation of Applicable Laws); and (ii) BeiGene shall, at its cost and expense, orderly wind-down the conduct of any such Clinical Trial that is not assumed by AssemblyBio under clause (i) above.

(i) **Return of Confidential Information**. At the Disclosing Party's election, the Receiving Party will return (at Disclosing Party's expense) or destroy all tangible materials comprising, bearing, or containing any Confidential Information of the Disclosing Party relating to any Licensed Product that are in the Receiving Party's or its Affiliates' possession or control and provide written certification of such destruction (*except* to the extent any information is the Confidential Information of both Parties or to the extent that the Receiving Party has the continuing right to use the Confidential Information under this Agreement); *provided*, that, the Receiving Party may retain one copy of such Confidential Information for its legal archives. Notwithstanding anything to the contrary set forth in this Agreement, the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information, which will continue to be subject to the applicable confidentiality and non-use obligation under this Agreement.

(j) **Costs of Termination Activities**. Notwithstanding anything to the contrary in this Section 15.3, if BeiGene terminates this Agreement pursuant to Section 15.2(c), AssemblyBio will be responsible for the reasonable out-of-pocket costs incurred by BeiGene

directly in connection with the performance of the activities set forth in this Section 15.3. BeiGene will invoice AssemblyBio quarterly for the foregoing costs incurred by or on behalf of BeiGene, and AssemblyBio will pay the invoiced amounts within [* * *] after the date of any such invoice. If this Agreement is terminated for other reasons, BeiGene shall be responsible for the costs incurred in connection with the performance of such activities to the extent not otherwise set forth in this Section 15.3.

15.4 Continuation of Agreement in Lieu of Termination by BeiGene for Breach. Notwithstanding anything to the contrary in this Article 15, if BeiGene has the right to terminate this Agreement pursuant to Section 15.2(c), then, at BeiGene's option (which may be exercised by BeiGene by written notice to AssemblyBio within [* * *] of the date of delivery by BeiGene of the notice of termination), BeiGene may elect not to terminate this Agreement, in which case the rights and obligations of the Parties under this Agreement shall continue following the effective date of termination, including the License granted by AssemblyBio to BeiGene pursuant to Section 2.1 and the right of AssemblyBio to receive the milestone and royalty payments pursuant to Article 9; *provided* that AssemblyBio's rights and BeiGene's obligations under Sections 3.2, 3.3, 5.8, 8.2, 8.3 and 8.4(b) shall terminate (with respect to Sections 3.2, 3.3 and 5.8, only in relation to activities in the Territory, which sections shall remain effective for any global Development activities).

15.5 Survival. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to such expiration or termination. Without limiting the foregoing, the provisions of Article 1 (as applicable), Article 10, Article 11, Article 13 and Article 16 (as applicable), and Sections 2.4 (subject to Section 15.3(b)), 2.5, 2.8 (only to the extent any terms and conditions of the Upstream License set forth in Exhibit 2.8 survive the termination or expiration thereof or of any sublicense agreements by their express terms or by reasonable implication), 5.6, 5.9 (with respect to AssemblyBio's use rights), 5.10 (with respect to responsibility for subcontractors), 9.5, 9.8 through 9.10 (with respect to Sections 9.5, and 9.8 through 9.10, solely in connection with amounts accrued prior to termination or expiration of this Agreement but not paid as of the termination or expiration of this Agreement), 12.6, 13.5, 14.1, 14.2(c), 15.1, 15.3, 15.5, and 15.6 shall survive the expiration or termination of this Agreement for any reason.

15.6 Termination Not Sole Remedy. Termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding anything contained in this Agreement to the contrary, all other remedies shall remain available except as agreed to otherwise herein.

ARTICLE 16
MISCELLANEOUS

16.1 Standstill. BeiGene agrees that for a period of two years from and after the Effective Date (the "**Standstill Period**"), unless specifically invited by AssemblyBio, neither BeiGene, any of Affiliates, nor its and their representatives acting on behalf of BeiGene or its Affiliates shall (and BeiGene shall cause its Affiliates and its and their representatives not to), directly or indirectly:

(a) elect, propose or consummate, or announce an intention to effect or knowingly facilitate or encourage any other person to elect, propose or consummate: (i) the

acquisition of record or beneficial ownership of any voting securities of AssemblyBio or any rights to acquire such voting securities; (ii) any merger, consolidation, or business combination with AssemblyBio; (iii) any recapitalization, restructuring, liquidation, dissolution or other similar extraordinary transactions with respect to AssemblyBio; or (iv) any "solicitation" of "proxies" (as such terms are used in Regulation 14A of the Exchange Act) or consents to vote (whether or not related to the election or removal of directors) with respect to any voting securities of AssemblyBio, or the initiation, proposal, encouragement or solicitation of stockholders of AssemblyBio for the approval of any stockholder proposals with respect to AssemblyBio, or the solicitation, advisement or influence of any person with respect to the voting of any voting securities of AssemblyBio;

(b) form, join or in any way participate in a "group" as defined in Section 13(d)(3) or Section 14(d)(2) of the Exchange Act with respect to any voting securities of AssemblyBio or otherwise in connection with any of the foregoing;

(c) (i) call or seek to call any meeting of stockholders of AssemblyBio, including by written consent, or provide to any Third Party a proxy, consent or requisition to call any meeting of stockholders of AssemblyBio; (ii) seek representation on the Board of Directors of AssemblyBio; or (iii) seek the removal of any member of the Board of Directors or management of AssemblyBio; or

(d) publicly disclose any intention, plan or arrangement, whether written or oral, inconsistent with the foregoing;

provided, *however*, that (i) notwithstanding the foregoing, BeiGene shall not be restricted from [* * *] and (ii) BeiGene will cease to be bound by the provisions of clauses (a) through (d) above upon (A) the public announcement or entry by AssemblyBio into a definitive agreement with a Third Party for a transaction involving the acquisition of more than [* * *] of the outstanding equity securities of AssemblyBio or all or a substantial portion of the assets of AssemblyBio by way of merger, consolidation, business combination, tender or exchange offer, recapitalization, restructuring, sale, equity issuance or otherwise or (B) the public announcement by AssemblyBio that it has undertaken a process for the sale of more than [* * *] of the outstanding equity securities of AssemblyBio or all or a substantial portion of the assets of AssemblyBio by way of merger, consolidation, business combination, tender or exchange offer, recapitalization, restructuring, sale, equity issuance or otherwise.

16.2 Assignment. Except as provided in this Section 16.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the consent of the other Party; *provided*, *however*, that (and notwithstanding anything elsewhere in this Agreement to the contrary) either Party may, without the written consent of the other Party, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate of such Party (for so long as such entity remains an Affiliate of such Party) and (a) BeiGene may, without the written consent of AssemblyBio, assign this Agreement and its rights and obligations hereunder (or under a transaction under which this Agreement is assumed) in connection with the transfer or sale of all or substantially all of its assets or business, or in the event of its merger or consolidation or similar transaction; and (b) AssemblyBio may, without the written consent of BeiGene, assign this Agreement and its rights and obligations hereunder (or under a transaction under which this Agreement is assumed) in

connection with the transfer or sale of all or substantially all of its assets or business, or in the event of its merger or consolidation or similar transaction. Any attempted assignment not in accordance with this Section 16.2 shall be void. Any permitted assignee shall expressly assume all assigned obligations of its assignor under this Agreement in writing. Section 14.2 of Exhibit 2.8 shall apply to any encumbrance, pledge or hypothecation of either Party's rights granted in this Agreement.

16.3 Extension to Affiliates. Except as expressly set forth otherwise in this Agreement, each Party shall have the right to extend the rights and obligations granted in this Agreement to one or more of its Affiliates by providing written notice to the other Party. All applicable terms and provisions of this Agreement, *except* this right to extend, shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the Party extending such rights and obligations. The Party extending the rights and obligations granted hereunder shall remain primarily liable for any acts or omissions of its Affiliates.

16.4 Severability. Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Applicable Laws, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision which conforms as nearly as possible with the original intent of the Parties.

16.5 Governing Law; English Language. This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the patent laws of the United States without reference to any rules of conflict of laws. This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.

16.6 Dispute Resolution.

(a) If any dispute, claim or controversy of any nature arising out of or relating to this Agreement, including any action or claim based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement (each, a "**Dispute**"), arises between the Parties and the Parties cannot resolve such Dispute through good faith discussions, within [* * *] of a written request by either Party to the other Party ("**Notice of Dispute**"), either Party may refer the Dispute to Executive Officers of each Party for resolution. Each Party, within [* * *] after a Party has received such written request from the other Party to so refer such Dispute, shall notify the other Party in writing of the specific Executive Officer to whom such dispute is referred. If, after an additional [* * *] after the Notice of Dispute, such Executive Officers have not succeeded in negotiating a resolution of the Dispute, and a Party wishes to pursue the matter, each such Dispute, controversy or claim that is not an "Excluded Claim" (defined below) shall be finally resolved by binding arbitration administered by JAMS ("**JAMS**") (or any successor entity thereto) pursuant to its arbitration rules and procedures then in effect (the "**Rules**"), as modified in this Section 16.6.

(b) The arbitration shall be conducted by a tribunal of arbitrators experienced in the business of pharmaceuticals. The tribunal shall be compromised of three (3) arbitrators, one of whom shall be nominated by each Party and a third of whom, who shall serve as the presiding

arbitrator, shall be nominated by mutual agreement of the two party-nominated arbitrators. If the two party-nominated arbitrators do not nominate the third arbitrator within [* * *] of the second arbitrator's appointment, then the third arbitrator shall be appointed by JAMS. If the issues in dispute involve scientific, technical or commercial matters, the arbitrators chosen hereunder shall engage experts that have educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, as necessary to resolve the dispute. Within [* * *] after initiation of arbitration, the Parties shall select the arbitrators. The place of arbitration shall be New York City, New York, and all proceedings and communications shall be in English.

(c) Prior to the arbitrators being selected, either Party, without waiving any remedy under this Agreement, may seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party until final resolution of the issue by the arbitrator or other resolution of the controversy between the Parties. Once the arbitrators have been selected, either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved, and either Party may apply to a court of competent jurisdiction to enforce interim injunctive relief granted by the arbitrators. Any final award by the arbitrators may be entered by either Party in any court having appropriate jurisdiction for a judicial recognition of the decision and applicable orders of enforcement. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. Each Party shall bear its own costs and expenses and attorneys' fees and an equal share of the arbitrators' fees and any administrative fees of arbitration, unless the arbitrators agree otherwise.

(d) Except extent necessary to confirm an award or as may be required by law, neither a Party nor the arbitrators may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable proceeding based on the dispute, controversy or claim would be barred by the applicable New York statute of limitations.

(e) As used in this Section 16.6, the term "**Excluded Claim**" means any dispute, controversy or claim that concerns (i) the validity, enforceability or infringement of any patent, trademark or copyright, or (ii) any antitrust, anti-monopoly or competition law or regulation, whether or not statutory. Any Excluded Claim may be submitted by either Party to any court of competent jurisdiction over such Excluded Claim.

16.7 Resolution of Certain Disputes.

(a) **Application to Certain Disputes**. The provisions of this Section 16.7 shall apply with respect to any dispute that has not been resolved within the [* * *] period following referral to Executive Officers described in Section 16.6(a), where such dispute concerns (i) [* * *], (ii) [* * *], and (iii) other matters that the Parties mutually agree should be subject to the dispute resolution mechanism set forth under this Section 16.7 (an "**Expert Dispute**").

(b) **Resolution by Expert**. If the Parties do not reach a mutually acceptable resolution as to an Expert Dispute within the [* * *] period following referral to Executive Officers described in Section 16.6(a), then upon written notice by either Party (an "**Expert Resolution**

Notice"), the Expert Dispute shall be resolved by a final, binding determination by an independent expert in the manner described in this Section 16.7.

(c) **Selection of Expert and Submission of Positions**. The Parties shall select and agree upon a mutually acceptable independent Third Party expert who is neutral, disinterested and impartial, and has at least [* * *] of commercial pharmaceutical industry experience (the "**Expert**"). If the Parties are unable to mutually agree upon an Expert within [* * *] following the delivery of the Expert Resolution Notice, then upon request by either Party, then the Expert shall be an arbitrator appointed by JAMS, which arbitrator need not have the above-described experience. Once the Expert has been selected, each Party shall within [* * *] following selection of the Expert provide the Expert and the other Party with a written report setting forth its position with respect to the substance of the Expert Dispute and may submit a revised or updated report and position to the Expert within [* * *] of receiving the other Party's report. If so requested by the Expert, each Party shall make oral submissions to the Expert based on such Party's written report delivered pursuant to this Section 16.7(c), and each Party shall have the right to be present during any such oral submissions.

(d) **JAMS Supervision**. In the event the Expert is a JAMS arbitrator selected by JAMS as provided in Section 16.7(c) above, the matter shall be conducted as a binding arbitration in accordance with JAMS procedures, as modified by this Section 16.7 (including that the arbitrator shall adopt as his or her decision the position of one Party or the other, as described in Section 16.7(c)). The arbitrator shall retain a neutral, disinterested and impartial Third Party expert with experience relevant to the specific subject matter of the particular Expert Dispute to assist in rendering such decision, and the expenses of such expert shall be shared by the Parties as costs of the arbitration.

(e) **Determination by the Expert**. The Expert shall, no later than [* * *] after the last submission of the written reports and, if any, oral submissions, select one of the Party's positions as his or her final decision, and shall not have the authority to modify either Party's position or render any substantive decision other than to so select the position of either BeiGene or AssemblyBio as set forth in their respective written report (as initially submitted, or as revised in accordance with Section 16.7(c), as applicable). The Parties agree that the decision of the Expert shall be the sole, exclusive and binding remedy between them regarding any Expert Dispute presented to the Expert, and the Expert's decision shall become the decision of the JSC on the matter.

(f) **Location; Costs**. Unless otherwise mutually agreed upon by the Parties, the location and costs of any dispute resolution under this Section 16.7 shall be as set forth in Section 16.6.

(g) **Timetable for Completion**. The Parties shall use, and shall direct the Expert to use, best efforts to resolve any Expert Dispute within [* * *] after the selection of the Expert, or if resolution within [* * *] is not reasonably achievable, as determined by the Expert, then as soon thereafter as is reasonably practicable.

16.8 Force Majeure. Neither Party shall be responsible to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder (excluding, in each case, the obligation to make payments when due) if such delay or

nonperformance is caused by strike, fire, flood, earthquake, accident, war, act of terrorism, act of God or of the government of any country or of any local government, or by any other cause unavoidable or beyond the control of any Party hereto. In such event, the Party affected will use reasonable efforts to resume performance of its obligations and will keep the other Party informed of actions related thereto. If any such failure or delay in a Party's performance hereunder continues for more than [* * *], the other Party may terminate this Agreement upon written notice to he delayed Party.

16.9 Waivers and Amendments. The failure of any Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. No waiver shall be effective unless it has been given in writing and signed by the Party giving such waiver. No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

16.10 Relationship of the Parties. Nothing contained in this Agreement shall be deemed to constitute a partnership, joint venture, or legal entity of any type between AssemblyBio and BeiGene, or to constitute one as the agent of the other. Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give any Party the power or authority to act for, bind, or commit the other.

16.11 Notices. All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (*i.e.*, pdf file), and sent as an attachment to an e-mail message, where, when such message is received, a read receipt e-mail is received by the sender (and such read receipt e-mail is preserved by the Party sending the notice), *provided* that a copy is promptly sent by an internationally recognized overnight delivery service (receipt requested) (although the sending of the e-mail message shall be when the notice is deemed to have been given), or (b) the earlier of when received by the addressee or [* * *] after it was sent, if sent by registered letter or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses and e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):

If to AssemblyBio:

Assembly Biosciences, Inc.
331 Oyster Point Blvd., 4th Floor
South San Francisco, CA 94080
Attention: Chief Legal and Business Officer
E-mail address: [* * *]

with copies to:

Ropes & Gray LLP
36F Park Place
1601 Nanjing Road West
Shanghai, China 200040
Attention: [* * *]
Email address: [* * *]

If to BeiGene:

BeiGene, Ltd.
c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue
Camana Bay
PO Box 1348
Grand Cayman, KY1-1108,
Cayman Islands
Attention: Chief Financial and Strategy Officer
E-mail address: [* * *]

With copies to:

BeiGene, Ltd.
55 Cambridge Parkway, Suite 700W
Cambridge, MA 02142
Attn: Senior Vice President, General Counsel
E-mail address: [* * *]

16.12 Further Assurances. BeiGene and AssemblyBio hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all documents and take any action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

16.13 Compliance with Law. Each Party shall perform its obligations under this Agreement in accordance with all Applicable Laws. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Laws.

16.14 No Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, *except* as otherwise expressly provided for in this Agreement.

16.15 Entire Agreement. This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter hereof and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter. The Parties acknowledge and agree that, as of the Effective Date, all Confidential Information disclosed pursuant to the Confidentiality Agreement by a Party or its Affiliates shall be included in the Confidential Information subject to this Agreement and the Confidentiality Agreement is hereby superseded in its entirety; provided, that the foregoing shall not relieve any Person of any right or obligation accruing under the Confidentiality Agreement prior to the Effective Date. "**Confidentiality Agreement**" means the Non-Disclosure Agreement between AssemblyBio and BeiGene dated [* * *].

16.16 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

16.17 Expenses. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

16.18 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

16.19 Construction. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

16.20 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

16.21 Export. Each Party acknowledges that the laws and regulations of the United States restrict the export and re-export of commodities and technical data of United States origin. Each Party agrees that it will not export or re-export restricted commodities or the technical data of the other Party in any form without appropriate United States and foreign government licenses.

16.22 Notification and Approval. In the event that this Agreement or the transaction(s) set forth herein are subject to notification or regulatory approval in one or more countries, then development and commercialization in such country(ies) will be subject to such notification or regulatory approval. The Parties will reasonably cooperate with each other with respect to such notification and the process required thereunder, including in the preparation of any filing. BeiGene will be responsible for any and all costs, expenses, and filing fees associated with any such filing.

[*Remainder of page left blank intentionally.*]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

ASSEMBLY BIOSCIENCES, INC.

By: /s/ Jason A. Okazaki
Name: Jason A. Okazaki
Title: Chief Legal and Business Officer

[Signature Page to Collaboration Agreement]

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives.

BEIGENE, LTD.

By: /s/ Guillaume Vignon, Ph.D.
Name: Guillaume Vignon, Ph.D.
Title: Senior Vice President, Business Development

List of Exhibits

Exhibit 1.56	Structure of Listed Compounds
Exhibit 2.1	Upstream License Provisions Related to License Grant
Exhibit 2.8	Applicable Upstream License Provisions
Exhibit 5.2(c)	ABI-H0731 Initial Development Plan
Exhibit 5.4(e)	Cost Sharing Examples
Exhibit 5.5(c)	AssemblyBio Ancillary Trials and Budget
Exhibit 11.4	Joint Press Release
Exhibit 12.2(a)	Scheduled Patent Rights
Exhibit 12.2(m)	Assignment Related to Scheduled Patent Rights
Exhibit 14.6	Upstream License Provisions Related to IP Prosecution and Enforcement

EXHIBIT 2.1
UPSTREAM LICENSE PROVISIONS RELATED TO LICENSE GRANT

2 **Definitions**: For the purposes of this Exhibit 2.1 and the Agreement, the following words and phrases have the meanings assigned to them below. Please refer to Exhibit 2.8 for the definition of other capitalized terms.

"Agreement" referenced in this Exhibit 2.1 refers to the Upstream License.

2.3 **Field**: Diagnostics and therapeutics.

2.5 Licensed Product: Any product: (i) the making, using or selling of which, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims (without giving effect to any safe harbor from infringement under 35 U.S.C. 271 (e)(1)); or (ii) that is made by, uses, or is used by a process that, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims.

2.8 Patent Rights:

2.8.1 The patent applications (including provisionals) filed or to be filed as listed on Exhibit A;

2.8.2 All U.S. patent applications directly or indirectly claiming priority to the abovereferenced patents or applications, including divisionals, continuations, and claims in continuations-in-part applications that are entitled to the priority filing date of any of the above;

2.8.3 Foreign equivalent applications;

2.8.4 Patents issuing from the above applications;

2.8.5 Reissues, re-examinations and extensions of the above, supplementary protection certificates and any patents issuing therefrom; and

2.8.6 Any of the foregoing during reissue, re-examination, or post grant review proceedings.

2.10 Sublicensee: A non-Affiliate third party to whom Assembly has granted a Sublicense pursuant to and in accordance with Article 3 of this Agreement. "Sublicense" is an arms- length agreement in which Assembly:

2.10.1 Grants or sublicenses any of the rights granted hereunder;

2.10.2 Agrees not to assert the Patent Rights or agrees not to sue, prevent, or seek a legal remedy for the practice of same; or

2.10.3 Has agreed to do any of the foregoing, including but not limited to licenses, option agreements, right of first refusal agreements, standstill agreements,

settlement agreements, co-development agreements, co-promotion agreements, joint venture agreements, or other agreements.

2.12 Term: Commencing on the Effective Date and continuing until the expiration of the last to expire of the patents in the Patent Rights unless earlier terminated in accordance with this Agreement.

2.13 Territory: Anywhere in the world, except those countries to which export of technology or goods is prohibited by applicable United States export control laws or regulations.

2.14 Valid Claim: A claim of a pending Patent Rights patent application or of an issued and unexpired Patent Rights patent, in each case that has not lapsed or been held revoked, invalid or unenforceable by a court or other governmental agency of competent jurisdiction in a decision or order that is not subject to appeal, provided that if a pending patent application has not issued within five (5) years from receiving a first US office action or foreign equivalent, the claims of such patent application will no longer be considered Valid Claims hereunder.

3 **Grant**: Subject to the terms and conditions of this Agreement and in consideration of Assembly's satisfaction of its obligations hereunder, IURTC hereby grants to Assembly and Assembly hereby accepts, the following license during the Term in the Territory:

3.1 An exclusive license to IURTC's and the Institutions' ownership rights in the Patent Rights, to make, have made, use, offer for sale, sell, and import Licensed Products in the Field.

3.2 The rights licensed to Assembly hereunder, except for the right to grant Sublicenses, may be extended to Affiliates provided that each such Affiliate first agrees in a written agreement to be bound by the terms and conditions of this Agreement as Assembly is bound, and such agreement: (a) names IURTC as a third party beneficiary; (b) terminates upon termination of this Agreement; and (c) is not transferable. Any Affiliate that desires to exercise any of the rights granted hereunder will enter into such written agreement with Assembly prior to exercising such rights. Assembly will deliver to IURTC a copy of said agreement and any amendment thereto within thirty (30) days of each execution. Assembly agrees to be fully responsible for the performance of such Affiliates and liable for their compliance herewith.

3.3 Assembly may grant Sublicenses to non-Affiliate third parties under this Agreement. Only Assembly, and not its Affiliates, is permitted to grant Sublicenses. Notwithstanding the foregoing, Sublicensees may grant sub-sublicenses (through multiple tiers) under the Agreement solely: (i) to their Affiliates, provided that any such sub-sublicenses shall automatically terminate if the sub-sublicensee party thereto ceases to be an Affiliate of the Sublicensee; (ii) subject to the terms of the Sublicense, to contract research organizations, distributors and other third party subcontractors for the sole purpose of performing

Sublicensee's obligations under the Sublicense; and (iii) to any other third party subject to IURTC's prior written consent, not to be unreasonably withheld, conditioned or delayed.

3.3.1 Any Sublicense granted by Assembly under this Agreement will be consistent with the terms and conditions of this Agreement and will:

3.3.1.1 Contain the terms and conditions set forth in definition 2.6 and the definitions it references, and in paragraphs 3.4, 3.6, 3.7, 6.3, 8.5, 8.6, 9.7, 16.6, and 16.8, and in Article 7 modified only to indicate that Sublicensee is under the same obligations as Assembly;

3.3.1.2 Contain the terms and conditions set forth in paragraph 6.2 and the definitions it references modified only to indicate that the Sublicensee is obligated to Assembly as Assembly is to IURTC; and

3.3.1.3 Contain the terms and conditions set forth in Articles 11, 12, and paragraph 7.5, modified only to indicate that the Sublicensee is obligated to IURTC and IU as Assembly is obligated to IURTC and IU hereunder.

3.3.2 If Assembly voluntarily enters bankruptcy or receivership, or if an involuntary bankruptcy action is filed against Assembly and not dismissed within ninety (90) days, then upon notice from IURTC, royalties based on Sublicensee's Net Sales and Sublicensing Revenue then or thereafter due to Assembly will become directly due and owing to IURTC for the account of Assembly. IURTC will remit to Assembly any amounts received that exceed the sum actually owed by Assembly to IURTC.

3.3.3 Within thirty (30) days of the effective date of any Sublicense, Assembly will provide IURTC a complete copy of the Sublicense and all exhibits thereto, along with Assembly's representation and warranty that no prior, contemporaneous, planned, or proposed contractual relationships between Assembly and Sublicensee contain consideration to Assembly reasonably attributable to the sublicensed rights. If the original Sublicense is written in a language other than English, the copy of the Sublicense and all exhibits thereto will be accompanied by a complete translation written in English. Assembly represents and warrants that such translation will be a true and accurate translation of the Sublicense and its exhibits.

3.3.4 Assembly agrees to be fully responsible for the performance of its Sublicensees hereunder and any sub-sublicensees under any sub-sublicenses granted by Sublicensee. Any act or omission by a Sublicensee or sub-sublicensee that would be a breach of this Agreement if imputed to Assembly will be deemed to be a breach by Assembly of this Agreement.

3.4 IURTC and the Institutions retain the right to practice under the Patent Rights for noncommercial educational and research purposes and permit other universities and nonprofit research institutes to do the same for non-commercial educational and research purposes.

Assembly may not in any way restrict the rights of IU, other universities or non-profit research institutions, or their faculty, staff, students, or employees from publishing the results of their research related to the Patent Rights.

3.5 This Agreement provides Assembly and Sublicensees no ownership rights of any kind in the Patent Rights, provided that the Parties acknowledge that Assembly has joint ownership rights in certain Patent Rights as set forth on Exhibit A. All ownership rights, other than such joint ownership rights owned by Assembly, remain the property of the Institutions and/or IURTC.

3.6 In accordance with 35 U.S.C. §§ 200-212, 37 C.F.R. Part 401, and in the relevant government research contracts with the Institutions, the United States government retains certain rights to inventions arising from federally supported research or development. Under these laws and implementing regulations, the government may impose requirements on such inventions. To the extent applicable, such rights and requirements include without limitation (i) the grant of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the government any of the Patent Rights throughout the world, and (ii) the requirement that Licensed Products used or sold in the U.S. will be manufactured substantially in the U.S. The rights granted in this Agreement are expressly made subject to these laws and regulations as they may be amended from time to time. Assembly will be required to abide by all applicable laws and regulations. IURTC agrees to cooperate with Assembly in connection with attempting to secure any waiver of any obligations under 35 U.S.C. §204.

13.5 Upon termination of this Agreement, Assembly will promptly notify its Sublicensees of such termination. Any rights previously granted by Assembly under any Sublicense hereunder will be automatically revoked thirty (30) days following the effective date of termination of this Agreement. However, Sublicensees have the right to enter into a written license agreement with IURTC before their Sublicense is revoked, through which such Sublicensee will become bound to IURTC on substantially the same terms and conditions (including financial terms) as it was bound to Assembly under the Sublicense, but only to the extent that each financial term is no less favorable to IURTC than those set forth in Article 5 and paragraphs 9.3 and 9.4, and provided that the Sublicense does not impose any obligations on IURTC in excess of those imposed under this Agreement. If any Sublicensee desires to enter into such a license agreement, it will be wholly the responsibility of that Sublicensee to notify IURTC of such desire within thirty (30) days after the effective date of termination of this Agreement. IURTC hereby agrees to enter into such written license agreement, with modifications as is reasonably necessary to accommodate the functional and structural differences between Assembly and IURTC. Failure of a Sublicensee to timely enter into such a license agreement will automatically result in the termination of the Sublicense and all rights granted thereunder.

EXHIBIT 2.8
APPLICABLE UPSTREAM LICENSE PROVISIONS

All terms and conditions in this Exhibit 2.8 which shall be considered an integral part of the terms and conditions of the Collaboration Agreement, and, pursuant to Section 3.3.1 of the Agreement:

- The terms and conditions set forth in definition 2.6 and the definitions it references, and in paragraphs 3.4, 3.6, 3.7, 6.3, 8.5, 8.6, 9.7, 16.6, and 16.8, and in Article 7 shall be considered modified only to indicate that BeiGene is under the same obligations as AssemblyBio;
- The terms and conditions set forth in paragraph 6.2 and the definitions it references shall be considered modified only to indicate that the BeiGene is obligated to AssemblyBio as AssemblyBio is to IURTC; and
- The terms and conditions set forth in Articles 11, 12, and paragraph 7.5 shall be considered modified only to indicate that the BeiGene is obligated to IURTC and IU as AssemblyBio is obligated to IURTC and IU hereunder.

2 **Definitions**: For the purposes of this Exhibit 2.8 and the Agreement, the following words and phrases have the meanings assigned to them below.

"Agreement" referenced in this Exhibit 2.8 refers to the Upstream License.

"Collaboration Agreement" referenced in this Exhibit 2.8 refers to the Collaboration Agreement by and between Assembly Biosciences, Inc. and BeiGene, Ltd. dated July 17, 2020.

"Effective Date" for the Agreement is September 3, 2013.

"Institutions" means collectively, The Scripps Research Institute and Indiana University ("IU").

2.1 Affiliate: Any person or entity that, directly or indirectly, owns or controls Assembly or that is owned or controlled by or under common ownership or control with Assembly. Own(s) or control(s) means:

2.1.1 Direct or indirect ownership of at least 50% of the outstanding voting securities of a corporation;

2.1.2 The right to receive at least 50% of the earnings of the person, corporation, or other entity in question; or

2.1.3 The right to control the business decisions of the person, corporation, or other entity in question.

2.2 Development Plan: Assembly's good faith, bona fide plan for the development, manufacture, promotion, importation, use, sale and/or marketing of Licensed Products. The Development Plan will include, at a minimum:

2.2.1 A definition and/or specification of each Licensed Product planned for development;

2.2.2 Tasks to be performed by Assembly, its contractors and/or Sublicensees to develop each Licensed Product to the point of commercialization, including estimated time schedules for specific tasks;

2.2.3 Tasks to be performed to achieve any regulatory approval or other certification of each Licensed Product, including estimated time schedules for each; and

2.2.4 Identification of the primary country(ies) in which Assembly plans to sell each Licensed Product and a good faith estimate of time of First Commercial Sale in the primary country(ies).

2.3 Field: Diagnostics and therapeutics.

2.4 Licensed Product: Any product: (i) the making, using or selling of which, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims (without giving effect to any safe harbor from infringement under 35 U.S.C. 271 (e)(1)); or (ii) that is made by, uses, or is used by a process that, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims.

2.6 Net Sales: The fair market cash value of all value, compensation, and payments received from the Sale of Licensed Products, less the following:

2.6.1 Trade, quantity, and cash rebates on Licensed Products actually provided to third parties;

2.6.2 Credits, allowances, or refunds, not to exceed the original invoice amount, for actual claims, damaged goods, rejections, or returns of Licensed Products; and

2.6.3 Excise, sale, use, value added, or other taxes, other than income taxes, that are included in the amounts received and that are paid by Assembly or Sublicensees for Licensed Products.

In the event that a Licensed Product is bundled or integrated with one or more other products (such Licensed Product together with such other product(s), a "Bundled Product"), Net Sales will be calculated on the basis of the total invoice price of the Bundled Product multiplied by a fraction, the numerator of which will be the list price of the Licensed Product and the denominator of which will be an amount equal to the aggregate of all list prices of the Licensed Product and all other products in the applicable Bundled Product. In the event that there is Bundled Product and the list price of the Licensed Product and each other product in the applicable Bundled Product cannot be determined, then (a) the parties will negotiate in good faith to agree in writing on the relative value of the

Licensed Product and each other product in the applicable Bundled Product, which determination will be based upon sales prices for comparable products or processes, and (b) such relative value(s) will be used in calculating Net Sales. The deductions set forth in clauses 2.6.1 through 2.6.3 will be applied to the total invoice price for the applicable Bundled Product prior to calculating Net Sales of the Licensed Product.

2.7 Party: Individually, IURTC or Assembly. Collectively, IURTC and Assembly may be referred to as the "Parties."

2.8 Patent Rights:

2.8.1 The patent applications (including provisionals) filed or to be filed as listed on Exhibit A;

2.8.2 All U.S. patent applications directly or indirectly claiming priority to the abovereferenced patents or applications, including divisionals, continuations, and claims in continuations-in-part applications that are entitled to the priority filing date of any of the above;

2.8.3 Foreign equivalent applications;

2.8.4 Patents issuing from the above applications;

2.8.5 Reissues, re-examinations and extensions of the above, supplementary protection certificates and any patents issuing therefrom; and

2.8.6 Any of the foregoing during reissue, re-examination, or post grant review proceedings.

2.9 The terms Sale, Sold, Sell: Any transaction in which a Licensed Product is exchanged or transferred for value, including without limitation sales, leases, licenses, rentals, provision of services through the use of Licensed Products, and other modes of distribution or transfer of a Licensed Product or its beneficial use. A Sale of a Licensed Product will be deemed to have been made when Assembly or its Sublicensee (or anyone acting on behalf of or for the benefit of Assembly or any of its Sublicensees) first invoices, ships, or receives value for a Licensed Product, whichever is earliest.

2.10 Sublicensee: A non-Affiliate third party to whom Assembly has granted a Sublicense pursuant to and in accordance with Article 3 of this Agreement. "Sublicense" is an arms- length agreement in which Assembly:

2.10.1 Grants or sublicenses any of the rights granted hereunder;

2.10.2 Agrees not to assert the Patent Rights or agrees not to sue, prevent, or seek a legal remedy for the practice of same; or

2.10.3 Has agreed to do any of the foregoing, including but not limited to licenses, option agreements, right of first refusal agreements, standstill agreements,

settlement agreements, co-development agreements, co-promotion agreements, joint venture agreements, or other agreements.

2.12 Term: Commencing on the Effective Date and continuing until the expiration of the last to expire of the patents in the Patent Rights unless earlier terminated in accordance with this Agreement.

2.14 Valid Claim: A claim of a pending Patent Rights patent application or of an issued and unexpired Patent Rights patent, in each case that has not lapsed or been held revoked, invalid or unenforceable by a court or other governmental agency of competent jurisdiction in a decision or order that is not subject to appeal, provided that if a pending patent application has not issued within five (5) years from receiving a first US office action or foreign equivalent, the claims of such patent application will no longer be considered Valid Claims hereunder.

3.3.2 If Assembly voluntarily enters bankruptcy or receivership, or if an involuntary bankruptcy action is filed against Assembly and not dismissed within ninety (90) days, then upon notice from IURTC, royalties based on Sublicensee's Net Sales and Sublicensing Revenue then or thereafter due to Assembly will become directly due and owing to IURTC for the account of Assembly. IURTC will remit to Assembly any amounts received that exceed the sum actually owed by Assembly to IURTC.

3.4 IURTC and the Institutions retain the right to practice under the Patent Rights for noncommercial educational and research purposes and permit other universities and nonprofit research institutes to do the same for non-commercial educational and research purposes. Assembly may not in any way restrict the rights of IU, other universities or non-profit research institutions, or their faculty, staff, students, or employees from publishing the results of their research related to the Patent Rights.

3.6 In accordance with 35 U.S.C. §§ 200-212, 37 C.F.R. Part 401, and in the relevant government research contracts with the Institutions, the United States government retains certain rights to inventions arising from federally supported research or development. Under these laws and implementing regulations, the government may impose requirements on such inventions. To the extent applicable, such rights and requirements include without limitation (i) the grant of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the government any of the Patent Rights throughout the world, and (ii) the requirement that Licensed Products used or sold in the U.S. will be manufactured substantially in the U.S. The rights granted in this Agreement are expressly made subject to these laws and regulations as they may be amended from time to time. Assembly will be required to abide by all applicable laws and regulations. IURTC agrees to cooperate with Assembly in connection with attempting to secure any waiver of any obligations under 35 U.S.C. §204.

3.7 Assembly will mark all Licensed Products made or sold in the United States in accordance with 35 U.S.C. §287(a), and will mark all Licensed Products made or sold in other countries in accordance with the laws and regulation then applicable in each such country.

6.2 Assembly will deliver to IURTC, with each payment made under paragraph 6.1, a written report describing the purpose of the payment and setting forth the calculation of the payment being made to IURTC, including the following:

6.2.1 For payments under paragraph 5.1, calculations of payments due in connection with Net Sales by Assembly, by each Affiliate, and by each Sublicensee on a country-by-country basis: the number of Licensed Products Sold; gross receipts for Sales; deductions as described in paragraph 2.6, giving totals by each type; and Net Sales.

6.2.2 For payments under paragraph 5.1 and 5.4, the serial numbers of the patent applications and patents in the Patent Rights that in Assembly's good-faith determination cover each Licensed Product.

6.2.3 For payments under paragraph 5.2, a description and list of amounts credited against the diligence maintenance fee.

6.2.4 For payments under paragraph 5.3, the name of the Sublicensee paying the Sublicensing Revenue to Assembly.

6.3 Assembly will maintain complete and accurate books of account and records that would enable an independent auditor to verify the amounts paid under this Agreement, and for otherwise verifying its performance hereunder. The books and records will be maintained for three (3) years following the quarter after submission of the reports required by this Article. Upon reasonable notice by IURTC, Assembly will give IURTC (or auditors or inspectors appointed by and representing IURTC) access to all books and records for Sales of Licensed Products to conduct, at IURTC's expense, an audit or review of those books and records. This access will be available no more than once every calendar year, during regular business hours, during the Term and for the three calendar years following the year in which termination or expiration occurs. Any underpayment will be promptly paid, with interest as set forth in paragraph 6.4, to IURTC. Any overpayment will be granted to Assembly as a credit against future payment. If the audit or review reports an underpayment by five percent (5%) or more for any fiscal quarter, Assembly will promptly reimburse IURTC for the costs and expenses of the accountants and auditors in connection with the review and audit.

7 **Confidentiality:**

7.1 The terms and conditions of Articles 4 and 5 and information exchanged between the Parties under Articles 4, 6, and 9, as well as any information designated by a Party in any reasonable manner as confidential within a reasonable time after it is delivered to the receiving Party, are Confidential Information.

7.2 During the Term and for a period of three (3) years thereafter, the receiving Party agrees to maintain in secrecy and not disclose to any third party any Confidential Information received, and to use reasonable measures to ensure the confidentiality of such Confidential Information. Receiving Party will use the Confidential Information received solely as necessary to perform its obligations and exercise its rights in accordance with the terms and conditions of this Agreement.

7.3 Confidential Information does not include information that:

7.3.1 Is or becomes publicly known through no fault of the receiving Party;

7.3.2 Was known to the receiving Party before disclosure by the disclosing Party as established by documentary evidence;

7.3.3 Is identical subject matter originally and independently developed by the receiving Party's personnel without knowledge or use of or access to any disclosing Party's Confidential Information as established by documentary evidence; or

7.3.4 Was disclosed to the receiving Party without restriction by a third party having a right to make the disclosure.

7.4 Notwithstanding the other terms of this Article 7,

7.4.1 Assembly may, to the extent necessary, use Confidential Information to secure governmental approval to clinically test or market a Licensed Product, to comply with a court order or governmental rule or regulation, or to show to a potential or actual sublicensee, contractor, investor, acquirer or professional adviser, subject to an appropriate confidentiality agreement (or in the case of professional advisers, ethical obligations). Assembly will, in any such use, take all reasonably available steps to maintain confidentiality of the disclosed information and to guard against any further disclosure.

7.4.2 IURTC may report consideration received under this Agreement and Assembly's progress under Article 4, including providing the Development Plans and reports, to the Institutions and the Inventors.

7.5 Neither Party may use the name of the other for any commercial, advertisement, or promotional purpose without the prior written consent of the other. Assembly may not use the name of the Institutions for any commercial, advertisement, or promotional purpose without the prior written consent of the Institutions. However, each Party may state that Assembly licensed from IURTC one or more of the patent applications and/or patents in the Patent Rights and may further include (i) Institutions' Inventors' names, (ii) invention titles and summaries, (iii) Field, and (iv) type and extent of license. The foregoing shall not restrict either Party from making disclosures or statements as required by law or regulation.

8.5 It is understood that IURTC and Assembly are subject to United States laws and regulation (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979) controlling the export of technical data, computer software, laboratory prototypes, and other commodities, and that such obligations hereunder are contingent upon compliance with applicable U.S. export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the U.S. Government and/or written assurances by Assembly that Assembly will not export data or commodities to certain foreign countries without prior approval of such agency. IURTC does not represent that a license is not required, or that, if required, such a license will be issued.

8.6 It is understood that IURTC and Assembly are subject to United States and foreign laws and regulations prohibiting bribery, including, but not limited to, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and that the obligations of IURTC and Assembly under this Agreement are contingent upon compliance with the U.S. Foreign Corrupt Practices Act. IURTC is not obligated to take any action that it believes in good faith may cause it to be in violation of the U.S. Foreign Corrupt Practices Act or other U.S. laws.

9.7 Assembly and IURTC agree that the Patent Rights will be extended by all means provided by law or regulation, including without limitation extensions provided under United States law at 35 U.S.C. §154(b) and 156. Assembly hereby agrees to provide IURTC with all necessary assistance in securing such extension, including without limitation, providing all information regarding applications for regulatory approval, approvals granted, and the timing of same. Assembly acknowledges that extension under 35 U.S.C. §156 must be applied for within sixty (60) days of the date that a Licensed Product receives permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use, and that Assembly's failure to promptly provide the necessary information or assistance to IURTC during such sixty day period will cause serious injury to IURTC, for which Assembly will be liable at law.

11 **Indemnification:**

11.1 Assembly will indemnify, defend, and hold harmless IURTC, the Institutions, their respective Board of Directors, trustees, employees, the Institutions' faculty, staff, employees, students, successors, assigns, independent contractors, and agents (collectively, "IURTC Indemnitees") from and against any and all judgments, liabilities, losses, or damages, (including all attorney fees and costs incurred by IURTC Indemnitees) (collectively, "Losses") in connection with any actions or claims brought by any third party arising out of, relating to, or incidental to the exercise of any rights or breach of any term or condition under this Agreement by Assembly or its Affiliates, successors or assigns, or Sublicensees (provided, however, that Assembly will have no obligation pursuant to the foregoing with respect to any Losses that result solely and exclusively from the gross negligence or willful misconduct of any IURTC Indemnitee), including but not limited to:

11.1.1 The use of any Patent Rights in the design, development, production, manufacture, sale or offer for sale, use, importation, lease, marketing or promotion of any Licensed Product;

11.1.2 Injury or death to any person, damage to property, or any injury to business, including, but not limited to, business interruption or damage to reputation, arising out of, relating to, or incidental to the use of the Patent Rights or a Licensed Product; and

11.1.3 Any third party claim that any use or licensing of the Patent Rights or development, provision, or use of Licensed Products violates or infringes a third party's intellectual property rights.

11.2 Assembly at its sole expense will defend third party claims. Assembly will have the right to conduct the defense of such actions. Assembly will consult with IURTC prior to and in conjunction with all significant issues, will keep IURTC informed of all proceedings, and will provide copies to IURTC of all pleadings, legal analyses, and other papers related to such actions. IURTC will provide reasonable assistance to Assembly in defending any such actions and IURTC Indemnitees may be represented by counsel of its choosing at its expense. Assembly will not settle or compromise any claim or action in a manner that imposes restrictions or obligations on IURTC Indemnitees or requires any financial payment or admission of liability by IURTC Indemnitees.

11.3 If Assembly fails to defend a claim or action for which it is required to provided indemnification under this Article 11 within twenty (20) days of learning of the same, in addition to and not in lieu of other rights and remedies, IURTC may assume the defense for the account of and at the risk of Assembly, and any resulting liability, including attorney fees, will be deemed conclusively to be a liability of Assembly. Assembly's failure or refusal to act is a material breach of this Agreement. If it is determined by a court of competent jurisdiction that such claim is not within Assembly's indemnification obligations under this Article 11 the foregoing will not apply, Assembly's failure or refusal to act will not be deemed a material breach, and any termination will be reversed.

12 **Insurance**:

12.1 Assembly will at all times comply, through insurance, with all statutory workers' compensation and employers' liability requirements covering all employees with respect to activities undertaken in performance of this Agreement.

12.2 In addition to the foregoing, Assembly and Sublicensees will obtain and maintain commercial general liability insurance with a reputable and financially secure insurance carrier prior to making, using, importing, offering to sell, or selling any Licensed Product, or engaging in any other act involving any Licensed Product or the Patent Rights, if such act could possibly create risk of a claim against IURTC Indemnitees for personal injury or property damage.

12.2.1 The insurance will identify IURTC as an additional insured and will provide that the carrier will notify IURTC in writing at least thirty (30) days prior to cancellation or material change in coverage.

12.2.2 The insurance will include coverage for product liability with a minimum of two million dollars ($2,000,000) per occurrence and five million dollars ($5,000,000)

annual aggregate, coverage for contractual liability, and all other coverages standard for such policies.

12.2.3 Insurance policies purchased to comply with this Article will be kept in force for at least five (5) years after the last Sale of Licensed Product.

12.3 At IURTC's request, such request to be made no more than annually, Assembly will provide IURTC with a certificate of insurance and notices of subsequent renewals for its insurance and that of any Sublicensee.

12.4 The specified minimum coverages and other provisions of this Article 12 do not constitute a limitation on Assembly's obligation to indemnify the IURTC Indemnitees under this Agreement.

14.2 The rights granted in this Agreement may not be encumbered, pledged, or hypothecated in any way by Assembly or any Sublicensee, including but not limited to secure any purchase, lease, or loan.

16.6 The provisions of this Agreement are severable in that if any provision in the Agreement is finally determined by a court of competent jurisdiction to be invalid or unenforceable, such invalidity or non-enforceability will not in any way affect the validity or enforceability of the remaining provisions or the validity or enforceability of such provision in any jurisdiction where valid and enforceable. Any invalid or unenforceable provision will be reformed by the Parties to effectuate their intent as evidenced on the Effective Date.

16.8 Assembly agrees that in the event an Institution's faculty or staff member serves Assembly in the capacity of consultant, officer, employee, board member, advisor, or other designation, pursuant to contract or otherwise, such Institution's faculty or staff member is subject to compliance with Institution's conflict of interest and conflict of commitment policies, including the obligation to complete a disclosure therefor, will serve in his or her individual capacity, as an independent contractor, and not as an agent or representative of IURTC or Institutions, that IURTC or Institutions exercises no authority or control over such faculty or staff member while acting in such capacity, that IURTC or Institutions receives no benefit from such activity, and that IURTC or Institutions assume no liability or obligation in connection with any such work or service undertaken by such faculty or staff member. Assembly further agrees that any breach, error, or omission by an Institutions faculty or staff member acting in the capacity set forth above in this paragraph will not be imputed or otherwise attributed to IURTC or Institutions, and will not constitute a breach of this Agreement by IURTC.

EXHIBIT 11.4
JOINT PRESS RELEASE

[*See attached.*]

CONFIDENTIAL

Press Release Targeted: Monday, July 20, 2020 at 3:30 am PT / 6:30 am ET

Assembly Biosciences and BeiGene Announce License and Collaboration Agreement in China for Assembly's Portfolio of Three Clinical-Stage Core Inhibitors for Chronic Hepatitis B Infection

-- BeiGene acquires exclusive development and commercialization rights to ABI-H0731, ABI-H2158, and ABI-H3733 in China --
-- Assembly receives $40 million upfront payment and is eligible to receive up to $500 million in potential development, regulatory, and sales milestone payments plus royalties on product sales --
-- Assembly to host webcast and conference call today at 8:30 am ET --

SOUTH SAN FRANCISCO, Calif., BEIJING, China and CAMBRIDGE, Mass, July 20, 2020 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB) and BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), today announced that the companies have entered into a collaboration in China for Assembly's portfolio of three clinical-stage core inhibitor candidates for the treatment of patients with chronic hepatitis B virus (HBV) infection.

Under the terms of the agreement, Assembly has granted BeiGene exclusive rights to develop and commercialize ABI-H0731, ABI-H2158 and ABI-H3733 in China, including Hong Kong, Macau, and Taiwan. ABI-H0731 and ABI-H2158 are both in ongoing Phase 2 clinical trials and ABI-H3733 is in Phase 1 development. BeiGene will be responsible for development, regulatory submissions, and commercialization in China. Assembly retains full worldwide rights outside of the partnered territory for the Company's HBV portfolio.

Assembly will receive an upfront cash payment of $40 million and is eligible to receive up to approximately $500 million in potential development, regulatory and net sales milestone payments pending successful development and commercialization of the licensed candidates. In addition, Assembly is eligible to receive tiered royalties of net sales. BeiGene will contribute initial funding for clinical development in China, after which the development costs for the territory will be shared equally by the parties.

"This collaboration with Assembly expands our portfolio beyond oncology to liver diseases, which are highly prevalent and represent a high unmet need in China," said John Oyler, Co-Founder, Chairman and Chief Executive Officer of BeiGene. "We are thrilled to collaborate with the Assembly team that has industry-leading expertise in this area to advance novel treatments for hepatitis B, with the ultimate goal of developing a cure. Since one-third of the world's individuals living with chronic hepatitis B are in China, we are committed to leveraging our capabilities to further develop these novel therapies for patients with HBV infection."

"Our goal for China has been to find a strong, trustworthy partner with a proven track record, and we are excited to collaborate with the experienced team at BeiGene, a premier scientific partner in

our industry," said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences. "BeiGene has world-class operations in China, enabling us to accelerate the clinical development and commercialization of our core inhibitors for this important market as well as globally. With up to 90 million individuals infected with HBV in China and given the significant unmet medical need, we and BeiGene are committed to advancing our novel core inhibitors for patients living with this chronic disease."

Assembly currently projects its $249 million in cash at March 31, 2020, together with these additional near-term sources of funding, will extend its funding of operations into the second half of 2022.

Goldman Sachs & Co. LLC is acting as exclusive financial advisor to Assembly Biosciences.

Assembly's Webcast and Conference Call Today
Management from Assembly Biosciences will host a webcast and conference call today at 5:30 am PT / 8:30 am ET. The live audio webcast with accompanying slides may be accessed through the "Events & Presentations" page in the "Investors" section of Assembly's website at https://investor.assemblybio.com/events-presentations. Alternatively, participants may dial (866) 438-0453 (domestic) or (409) 220-9366 (international) and refer to conference ID 4380778. Call participants are encouraged to connect at 5:15 am PT / 8:15 am ET to ensure a timely connection to the call or to utilize the webcast link for listen-only access.

The archived webcast will be available on Assembly's website beginning approximately two hours after the event and will be archived and available for replay for at least 30 days after the event.

About Assembly Biosciences' HBV Core Inhibitor Portfolio
Assembly's HBV portfolio includes three clinical-stage small molecule candidates, all of which are HBV core inhibitors that target multiple steps of the HBV lifecycle. In Phase 2 clinical trials, first-generation core inhibitor ABI-H0731 administered with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy has been well-tolerated, has shown statistically superior antiviral activity in HBV DNA suppression compared to NrtI therapy alone, and has demonstrated significant declines in pgRNA that may indicate decreased cccDNA levels. In the ongoing Phase 2 open-label extension trial, Assembly is beginning to transition patients off combination therapy, to then monitor for sustained virologic response (SVR).

Assembly's HBV portfolio also includes two more potent, second-generation candidates, ABI-H2158 in a Phase 2 clinical trial and ABI-H3733 in Phase 1 development.

Clinical data from ABI-H0731 and ABI-H2158 have been selected for presentation at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress, August 27-29, 2020.

About HBV
Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 million people worldwide with up to 90 million people in China, as estimated by the World Health

Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

About Assembly Biosciences
Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live microbial biotherapeutic candidates with Assembly's fully integrated platform, including a robust process for strain identification and selection, GMP manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology. For more information, visit assemblybio.com.

About BeiGene
BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Its 4,100+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline of novel therapeutics for cancer. BeiGene currently markets two internally-discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. BeiGene also markets or plans to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow on Twitter at @BeiGeneUSA.

Assembly's Forward-Looking Statements

The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ from those projected or implied. These risks and uncertainties include: Assembly and BeiGene's ability to initiate and complete clinical trials for ABI-H0731, ABI-H2158, and ABI-H3733 in the currently anticipated timeframes in China; safety and efficacy data from clinical studies may not warrant further development of Assembly's core inhibitor product candidates; the products subject to the collaboration may not achieve future milestones or be eligible for royalties; ABI-H0731, ABI-H2158 and ABI-H3733 may not receive regulatory approval under the currently anticipated timelines, or at all; Assembly's core inhibitor products may not be differentiated from other companies' candidates; Assembly may not observe sustained virologic response (SVR) in patients who are treated with its core inhibitors; and other risks identified from time to time in Assembly's reports filed with the U.S. Securities and Exchange Commission (the SEC). All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Readers are cautioned not to rely on these forward-looking statements. Assembly intends such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether resulting from new information, future events or otherwise.

BeiGene's Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding future development and potential commercialization of the licensed product candidates; potential payments payable to Assembly; the potential of the licensed product candidates to treat and possibly achieve SVR in HBV patients; and the parties' commitments and the potential benefits of the collaboration. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company's clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information

in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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# # #

EXHIBIT 14.6
UPSTREAM LICENSE PROVISIONS
RELATED TO IP PROSECUTION AND ENFORCEMENT

2 **Definitions**: For the purposes of this Exhibit 2.8 and the Agreement, the following words and phrases have the meanings assigned to them below. Please refer to Exhibit 2.8 for the definition of other capitalized terms.

"Agreement" referenced in this Exhibit 2.8 refers to the Upstream License.

2.1 Field: Diagnostics and therapeutics.

2.2 Licensed Product: Any product: (i) the making, using or selling of which, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims (without giving effect to any safe harbor from infringement under 35 U.S.C. 271 (e)(1)); or (ii) that is made by, uses, or is used by a process that, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims.

2.3 Patent Rights:

2.3.1 The patent applications (including provisionals) filed or to be filed as listed on Exhibit A;

2.3.2 All U.S. patent applications directly or indirectly claiming priority to the abovereferenced patents or applications, including divisionals, continuations, and claims in continuations-in-part applications that are entitled to the priority filing date of any of the above;

2.3.3 Foreign equivalent applications;

2.3.4 Patents issuing from the above applications;

2.3.5 Reissues, re-examinations and extensions of the above, supplementary protection certificates and any patents issuing therefrom; and

2.3.6 Any of the foregoing during reissue, re-examination, or post grant review proceedings.

2.4 Sublicensee: A non-Affiliate third party to whom Assembly has granted a Sublicense pursuant to and in accordance with Article 3 of this Agreement. "Sublicense" is an arms- length agreement in which Assembly:

2.4.1 Grants or sublicenses any of the rights granted hereunder;

2.4.2 Agrees not to assert the Patent Rights or agrees not to sue, prevent, or seek a legal remedy for the practice of same; or

2.4.3 Has agreed to do any of the foregoing, including but not limited to licenses, option agreements, right of first refusal agreements, standstill agreements, settlement agreements, co-development agreements, co-promotion agreements, joint venture agreements, or other agreements.

2.12 Term: Commencing on the Effective Date and continuing until the expiration of the last to expire of the patents in the Patent Rights unless earlier terminated in accordance with this Agreement.

2.13 Territory: Anywhere in the world, except those countries to which export of technology or goods is prohibited by applicable United States export control laws or regulations.

2.14 Valid Claim: A claim of a pending Patent Rights patent application or of an issued and unexpired Patent Rights patent, in each case that has not lapsed or been held revoked, invalid or unenforceable by a court or other governmental agency of competent jurisdiction in a decision or order that is not subject to appeal, provided that if a pending patent application has not issued within five (5) years from receiving a first US office action or foreign equivalent, the claims of such patent application will no longer be considered Valid Claims hereunder.

9.1 IURTC is the owner or co-owner of the Patent Rights and will have exclusive control of the preparation, filing, prosecution, issue, and maintenance of the Patent Rights. Maintenance includes but is not limited to post-issuance proceedings such as post-grant reviews, reissue proceedings, and re-examination proceedings. IURTC will select qualified patent counsel reasonably acceptable to Assembly to prepare, file, prosecute and maintain the Patent Rights. IURTC will keep Assembly fully informed of patent prosecution, will seek Assembly's comments and suggestions prior to taking material actions for the same, and will take all prosecution actions reasonably recommended by Assembly which would expand the scope of rights sought.

9.8 Notwithstanding anything in this Agreement to the contrary, the Parties acknowledge and agree that for the patent applications listed on Exhibit A that are identified as "Protein Modulator Patents" (including all associated Patent Rights) (such patent applications and associated Patent Rights, collectively, the "Protein Modulator Patent Rights") that Assembly is a co-owner of the Protein Modulator Patent Rights and, notwithstanding anything in Sections 9.1 through 9.7 to the contrary, the Parties agree that:

9.8.3 Assembly will not abandon the prosecution of any patent application or the maintenance of any patent under the Protein Modulator Patent Rights without prior written notice to IURTC. Upon receiving such written notice, IURTC, at its sole option, may take over the prosecution of any such patent application or the maintenance of any such issued patent in accordance with Sections 9.1 through 9.7.

10. **Third Party Infringement**:

10.1 The Parties will give prompt written notice to each other of any known or suspected infringement of the Patent Rights by a third party. Assembly at its sole expense has the right to attempt to abate any infringement of the Patent Rights in the Field. Assembly may initiate and prosecute actions against third parties for infringement and/or unfair trade practices, and if required by law, IURTC will permit any action to be brought in its name, including being joined as a party-plaintiff. Assembly will consult with IURTC prior to and in conjunction with all significant issues, will keep IURTC informed of all proceedings, and will provide copies to IURTC of all pleadings, legal analyses, and other papers related to such actions. IURTC will provide reasonable assistance to Assembly in prosecuting any such actions and will be compensated by Assembly for its reasonable out-of-pocket expenses, which IURTC will only be required to expend if Assembly has approved same for reimbursement. Absent IURTC's prior written consent, Assembly will not settle or compromise any claim or action in a manner that grants rights or concessions to a third party to the Patent Rights.

10.2 Any damages paid (including without limitation statutory damages, compensatory damages, lost profits damages, exemplary damages, increased damages, and awards of costs and attorney fees) will first be applied to reimbursement of Assembly's reasonable costs, expenses, and legal fees, including amounts Assembly has reimbursed to IURTC. Assembly will retain the remaining balance of such damages, subject to payment to IURTC of an amount based upon a reasonable approximation of the royalties and other amounts that Assembly would have paid to IURTC if Assembly had sold the infringing products rather than the infringer. Any special or punitive damages will be distributed [* * *] percent ([* * *]%) to Assembly and [* * *] percent ([* * *]%) to IURTC.

10.3 If Assembly fails or declines to take any action under paragraph 10.1 within sixty (60) days after learning of third party infringement or unfair trade practices, IURTC will have the right, but not the obligation, to take appropriate actions against any such third party at its sole expense and to retain all recovered damages. In such instances, Assembly will cooperate as requested by IURTC, and will be compensated by IURTC for its reasonable out-of-pocket expenses, which Assembly will only be required to expend if IURTC has approved same for reimbursement.

EXHIBIT 31.1

CERTIFICATION

I, John G. McHutchison, A.O., M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

By: /s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Thomas J. Russo, CFA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

By: /s/ Thomas J. Russo, CFA
Thomas J. Russo, CFA
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, John G. McHutchison, A.O., M.D., Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ John G. McHutchison, A.O., M.D.
John G. McHutchison, A.O., M.D.
Chief Executive Officer and President
(Principal Executive Officer)

Date: November 5, 2020

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the Company) for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on or about the date hereof (the Report), I, Thomas J. Russo, CFA, Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the Report.

/s/ Thomas J. Russo, CFA

Thomas J. Russo, CFA
Chief Financial Officer
(Principal Financial Officer)

Date: November 5, 2020